No. 07-192

Supreme Court, U.S.
FILED
AUG 14 2007
OFFICE OF THE CLERK

# In The Supreme Court of the United States

ADVANCED CARDIAC SOLUTIONS, P.C.;
CHARLES WALL,

*Petitioners,*

v.

CENTRAL ADMIXTURE PHARMACY SERVICES, INC.;
DR. GERALD D. BUCKBERG,

*Respondents.*

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

## PETITION FOR WRIT OF CERTIORARI WITH APPENDIX

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## QUESTIONS PRESENTED

Whether title to a patent covering a federally funded invention, and thus standing to pursue a claim for infringement of that patent, can be obtained from a federally funded non profit institution which purported to assign "whatever interest it had" without the approval of the Federal agency administering the funding agreement as required under the Bayh-Dole Act, 35 U.S.C. § 202(c) and (d)?

Whether title to a patent covering a federally funded invention, and thus standing to pursue a claim for infringement of that patent, can be obtained despite the admitted failure to execute and timely deliver a Confirmatory License in the United States Government as required by the Federal agency to obtain title in accordance with the Bayh-Dole Act?

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No publicly held company owns 10% or more of the stock of Petitioner.

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Advanced Cardiac Solutions, P.C. and Charles Wall hereby petition for a Writ of Certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit entered in this action on April 3, 2007 and issued as a Mandate on May 23, 2007.

## V. OPINIONS BELOW

The opinion of the Court of Appeals for the Federal Circuit is published at 482 F.3d 1347 and is reproduced in the Appendix beginning at page 1a. Rehearing was denied on May 16, 2007 and the order is reproduced in the Appendix at page 18a.

The opinion and final judgment of the United States District Court for the Northern District of Alabama is unreported and is reproduced in the Appendix beginning at page 19a.

The administrative decision of the Assistant Secretary of Health, Department of Health and Human Services is unreported and is reproduced in the Appendix beginning at page 71a.

## VI. JURISDICTION

The Court has jurisdiction as follows: the Court of Appeals for the Federal Circuit entered its decision on April 3, 2007, affirming the judgment of the Northern District of Alabama rendered in No. CV-00-2430-VEH. The Court of Appeals denied petitions for rehearing and rehearing en banc submitted by the parties on May 16, 2007. The Court of Appeals Mandate issued on May 23, 2007. The statutory basis for the District Court's subject matter jurisdiction was 28 U.S.C. § 1338(a). The statutory basis for the jurisdiction of the Court of Appeals was 28 U.S.C. § 1292(c)(2). This

Court has jurisdiction to review the case under 28 U.S.C. § 1254(1).

## VII. CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

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## VIII. STATEMENT OF THE CASE

This case raises an important federal question of first impression regarding the disposition of patent rights of

subject inventions[1] under the Bayh-Dole Act, 35 U.S.C. §§ 200-212, (App. p. 73a), and whether title, and thus Article III, Section 2 (App. p. 72a) standing to pursue actions based on such patents, can be obtained despite non-compliance with its provisions. Standing to sue is a threshold requirement in every federal action and the party bringing the action bears the bu len of establishing that it has standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 570 n.5 (1992).

The Patent Act provides that only "[a] patentee shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 281. (App. p. 83a). The term "patentee" comprises "not only the patentee to whom the patent was issued but also the successors in title to the patentee." 35 U.S.C. § 100(d). (App. p. 72a). The decision of the Court of Appeals for the Federal Circuit recites but ignores the long established precedents of this Court which hold that the presence of the patentee is necessary to maintain an infringement action under the Patent Laws. *Ind. Wireless Telegraph Co. v. Radio Corp.*, 269 U.S. 459, 466-67 (1926); *Waterman v. Mackenzie*, 138 U.S. 252 (1891); *Littlefield v. Perry*, 88 U.S. 205 (1874); *Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24 (1923); *Gayler v. Wilder*, 51 U.S. 477 (1850); *United States v. American Bell Telephone Co.*; *Hendrie v. Sayles*, 98 U.S. 546, 549 (1878).

There are no factual disputes implicated by the questions presented. It is uncontroverted that on August 2, 1985, Dr. Buckberg executed an assignment conveying all right title, and interest in and to the subject invention[2] to the

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[1] As defined by 35 U.S.C. § 201(e) (App. p. 74a).

[2] Between 1978 and 1991, Dr. Buckberg, as the primary investigator, and the Regents of the University of California (Regents), as the contracting institution, applied for and received funds from the National Institutes of Health (NIH) for research grant number HL-16292

Regents of the University of California (hereinafter Regents). (App. pp. 5a, 26a). On August 21, 1985 the Regents filed United States Patent application number 768,404 (the '404 application), entitled *Improved Cardioplegic Solutions*, to the exclusion of the named inventor, Dr. Gerald Buckberg, under the former provisions of 37 C.F.R. 1.32. The '404 application eventually issued as U.S. Patent No. 4,988,515 ('515) on January 29, 1991 in the name of the Regents as the assignee of record. (App. p. 26a).

As this Court holds, Dr Buckberg's assignment of the '404 application to the Regents completely divested him of any legal title to the '515 patent:

> Such an assignment may be made before the patent is obtained and provision is made that the patent may be issued to the assignee, provided the application is made and duly sworn to by the inventor himself, and the assignment is duly recorded. When so granted, the exclusive interest is vested as a legal estate in the assignee, who thus becomes the lawful holder of the invention, and the inventor himself is divested of the legal title.

*Hendrie*, 98 U.S. 546, 549 (1878).

As this Court held long ago, "Patent property is the creature of statute law and its incidents are equally so and depend upon the construction to be given to the statutes creating it and them, in view of the policy of Congress in their enactment." *Crown*, 261 U.S. 24 at 40 (1923). Because the '515 patent is a subject invention under the

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entitled "Surgical Reperfusion of the Ischemic Myocardium" (App. pp. 5a, 26a, 71a).

Bayh-Dole Act, the disposition of title to the invention is subject to the statutory provisions of the Act and its implementing regulations, 37 C.F.R. § 401, (App. pp. 83a-94a), promulgated under authority of 35 U.S.C. §§ 202(d) (App. 79a-80a) and 206 (App. p. 83a).

There is no question that the Regents took title to the subject invention subject to the provisions of the Bayh-Dole Act. Under 35 U.S.C. § 202(a), (App. p. 75a), the Regents' title was subject to certain express statutory restrictions which provide "The rights of the nonprofit organization[3] or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter." Thus, the Regents' authority to assign rights in a subject invention is specifically restricted by 35 U.S.C. § 202 (c)(7), (App. pp. 78a-79a), which expressly prohibits the Regents from assigning rights in a subject invention in the United States without the approval of the Federal agency, in this case, the NIH. 35 U.S.C. § 202(c)(7). (App. pp. 78a-79a).

On February 12, 1987, pursuant to its obligations under 37 C.F.R. § 401.14(f)(1), (App. p. 89a), to protect the Government's interest in the then pending '404 application, the University of California communicated its intention to abandon the '404 application to the NIH and referred the case to the NIH for final disposition.[4] (App. pp. 5a, 29a).

By letter dated March 11, 1987, Dr. Buckberg submitted a request to the NIH seeking ownership of the '404 application and also sought a waiver of the

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[3] As defined by 35 U.S.C. § 201(i). (App. p. 74a).

[4] Whether title reverted to the Government under 35 U.S.C. § 202(c)(2) as a result of this communication is immaterial to the final disposition of this case. It is the Plaintiffs' burden to establish its ownership in the patent.

Government's patent rights. (App. pp. 5a, 26a). In response to Dr. Buckberg's request by letter dated September 23, 1987, Dr. Robert E. Windom, Assistant Secretary for Department of Health and Human Services, communicated the Government's determination of patent rights in the '404 application. (App. pp. 71a, 5a, 26a). Dr. Windom treated Dr. Buckberg's request as one arising under 35 U.S.C. § 202(d). (App. p. 71a).

In his determination of patent rights, Dr. Windom stated *inter alia* that "[Dr. Buckberg] shall grant to the Government of the United States a nonexclusive, irrevocable, royalty-free license to use the invention for governmental purposes." *Id.* Dr. Windom's letter also states that he enclosed the form of the license to be executed by Dr. Buckberg and concludes by instructing Dr. Buckberg that "the executed copies of the license required by this determination should be submitted to the Patent Branch as soon as possible," and finally that "this determination will become effective upon receipt of the executed copy." *Id.* Dr. Buckberg acknowledged and accepted the Government's terms. *Id.*

Dr. Buckberg admitted that he never executed and delivered a confirmatory license to the United States Government, as required by the Government in its determination of patent rights. With respect to this admission under Fed. R. Civ. P. 36(b), the District Court held and the Federal Circuit affirmed that this fact was conclusively established. (App. pp. 5a, 26a, 30a).

On June 24, 1991, almost four years later, the Regents and Dr. Buckberg executed an Acknowledgement and Assignment of Rights to Invention purporting to assign the rights in the invention and patent to Dr. Buckberg. (App. pp. 5a-6a, 26a-27a).

There is no record of an authorization from the NIH for this assignment.

## IX. DECISIONS BELOW

In reaching their respective decisions both the District Court and the Federal Circuit held that Dr. Buckberg failed to comply with the requirements of the Bayh-Dole Act and the conditions imposed by the NIH in its determination of patent rights. (App. pp. 7a, 30a).

Despite these findings, each court relied on the Federal Circuit's decision in *Campbell Plastics Engineering & Mfg. v. Brownlee*, 389 F.3d 1243, 1250 (Fed Cir. 2004), for the unremarkable legal conclusion that the Federal Government has discretion to demand title to subject inventions under the Bayh-Dole Act for a contractor's failure to disclose a subject invention to the Government as permitted by 35 U.S.C. § 202(c)(1). (App. pp. 7a-8a, 30a-32a, 77a).

However, both the District Court and the Federal Circuit reached the anomalous and quite remarkable legal conclusion that Dr. Buckberg's failure to comply with the Bayh-Dole Act, its implementing regulations, and the NIH's determination that he execute a Confirmatory License in the U.S. Government, were matters that the courts were free to disregard. Instead the lower courts focused on whether the Government had taken any action to obtain title rather than whether Buckberg had satisfied the statutory and regulatory conditions precedent to his acquisition of title in the '515 patent. *Id.*

### 1. THE DISTRICT COURT'S DECISION

In finding that Dr. Buckberg possessed title to the '515 patent, the District Court held that:

> Based on the language of the statute and its interpretation by the Federal Circuit, the court determines that Dr. Buckberg's failure to comply with the Bayh-Dole Act leaves the patent subject to the Federal Government's discretionary right to take title to the '515 patent. In addition to the fact that this outcome is supported by the statutory language and applicable case law, the court finds that this conclusion furthers the purpose of the Bayh-Dole Act by interpreting the law to preserve the government's rights to inventions created through government funding and also by declining to interpret the law to provide additional defenses to alleged patent infringers. (App. p. 32a).

The District Court's decision negated the requirement imposed on Dr. Buckberg by the agency and vitiated the express prohibition against unauthorized transfers in the statute, thus, it neither furthers the purposes of the Bayh-Dole Act, nor is it supported by the statutory language of the Bayh-Dole Act. Moreover, 35 U.S.C. §§ 100(d), (App. p. 72a), and 281, (App. p 83a), already provide the necessary defense to all alleged patent infringers.

## 2. THE FEDERAL CIRCUIT'S DECISION

The Federal Circuit held that:

> When a violation occurs, the government can choose to take action; thus, title to the patent may be voidable. However, it is not void: title remains with the named inventors or their assignees. Nothing in the statute, regulations, or our case law indicates that title is automatically forfeited. The government must

> take an affirmative action to establish its title and invoke forfeiture. The defendants here have no basis to challenge the government's discretion in not invoking forfeiture. (App. p. 8a).

The Federal Circuit thus considered the question to be whether the Government had title to the invention by virtue of exercising its march in rights and disregarded the prohibition contained in 35 U.S.C. § 202(c)(7), (App. pp. 78a-79a), when it held that Buckberg's title to the invention was voidable, (App. p. 8a), an issue raised *sua sponte* by the Federal Circuit at oral argument. Critically, the Federal Circuit decision fails to address whether an effective transfer of title had been made to Plaintiff Buckberg, or how Article III, (App. p. 72a), jurisdiction is satisfied, if title remains in the non-party Regents by virtue of the Regents statutory inability to transfer title without agency authorization. As stated by this Court:

> The presence of the owner of the patent as a party is indispensable not only to give jurisdiction under the patent laws but also, in most cases, to enable the alleged infringer to respond in one action to all claims of infringement for his act, and thus either to defeat all claims in the one action, or by satisfying one adverse decree to bar all subsequent actions.

*Ind. Wireless*, 269 U.S. 459 at 468 (1926).

The other critical matter conspicuously absent from the decision of the Federal Circuit is any case law supporting its contention that the purported title is voidable, rather than void. This glaring omission from the Federal Circuit's decision is surprising since such a contention is in direct

conflict with long standing precedent of this Court. As stated by the Court in *Doolan v. Carr*:

> There is no question as to the principle that where the officers of the government have issued a patent in due form of law, which on its face is sufficient to convey the title to the land described in it, such patent is to be treated as valid in actions at law, as distinguished from suits in equity, ***subject, however, at all times to the inquiry whether such officers had the lawful authority to make a conveyance of the title. But if those officers acted without authority; if the land which they purported to convey had never been within their control, or had been withdrawn from that control at the time they undertook to exercise such authority, then their act was void — void for want of power in them to act on the subject-matter of the patent, not merely voidable;*** in which latter case, if the circumstances justified such a decree, a direct proceeding, with proper averments and evidence, would be required to establish that it was voidable, and should therefore be avoided. The distinction is a manifest one, although the circumstances that enter into it are not always easily defined. It is, nevertheless, a clear distinction, established by law, and it has been often asserted in this court, that even a patent from the government of the United States, issued with all the forms of law, may be shown to be void by extrinsic evidence, if it be such evidence as by its nature is capable of showing a want of authority for its issue.

> The decisions of this court on this subject are so full and decisive that a reference to a few of them is all that is necessary. *Polk's Lessee* v. *Wendall*, 9 Cranch, 87; *New Orleans* v. *United States*, 10 Pet. 662, 730; *Wilcox* v. *Jackson, dem. McConnell*, 13 Pet. 498, 509; *Stoddard* v. *Chambers*, 2 How. 284, 317; *Easton* v. *Salisbury*, 21 How. 426, 428; *Reichart* v. *Felps*, 6 Wall. 160: *Best* v. *Polk*, 18 Wall. 112, 117; *Leaven worth Railroad* v. *United States*, 92 U.S. 733; *Newhall* v. *Sanger*, 92 U.S. 761; *Sherman* v. *Buick*, 93 U.S. 209; *Smelting Co.* v. *Kemp*, 104 U.S. 636; *Steel* v. *Smelting Co.*, 106 U.S. 447; *Kansas Pacific Railway Co.* v. *Dunmeyer*, 113 U.S. 629, 642; *Reynolds* v. *Iron Silver Mining Co.*, 116 U.S. 687.

*Doolan v. Carr*, 125 U.S. 618, 624-25 (1887) (*emphasis added*).

This Court has recognized the applicability of the legal principles concerning the Government's disposition of real property to the patent law context, as the power over both emanate from the Constitution. *See United States v. American Bell Telephone Co.*, 128 U.S. 315, 358-59 (1888).

In this case, the Regents' authority to convey title in the '515 patent by way of assignment is expressly restricted by the Bayh-Dole Act, 35 U.S.C. § 202(c)(7), (App. 78a-79a). Application of the Bayh-Dole Act to the uncontested facts of this case precludes Dr. Buckberg from obtaining legal title in the '515 patent, which necessitates dismissal of the action.

## IX. REASONS FOR GRANTING THE PETITION

The Federal Circuit's decision that Dr. Buckberg held legal title to the '515 patent, despite his failure to comply with the Bayh-Dole Act, indicates its disregard of controlling precedent of this Court. (App. p. 8a). The Court should act immediately to correct the Federal Circuit's error, specifically with respect to the Bayh-Dole Act which establishes and standardizes the procedures for transfer of title in all Federally Funded inventions. This error, thus, has a tremendous impact on the rights of the Government, the tax-payers, as well the inventors and businesses obtaining rights through such funding. The Court should also grant this petition because the Federal Circuit's decision thwarts rather than furthers the Congressional purposes behind the Bayh-Dole Act. Finally, the Court should grant the petition because the Federal Circuit's decision conflicts with the decisions of other Circuit Courts of Appeal which hold that non-compliance with statutory provisions concerning accession to title preclude relief in the federal courts.

### 1. STATUTORY BASIS

The first basis for granting the petition is to correct the Federal Circuit's departure from established authority of this Court and its derogation of the statutory scheme enacted by Congress. As this Court held long ago: "Patent property is the creature of statute law and its incidents are equally so and depend upon the construction to be given to the statutes creating it and them, in view of the policy of Congress in their enactment." *Crown*, 261 U.S. 24 at 40 (1923). As is equally clear, when determining whether a party is properly before the courts as a patentee, the instruments by which that party claims its rights as patentee are necessarily reviewable by the courts. *Id.* at 39; *Ind. Wireless*, 269 U.S. 459 (1926); *Waterman*, 138 U.S. 252 (1891); *Littlefield*, 88 U.S. 205

(1874); *In Re Paper Bag Cases*, 105 U.S. 766 (1881); *Birdsell v. Shaliol*, 112 U.S. 485, 486 (1884).

Because Dr. Buckberg had divested himself of any interest in the '515 patent by virtue of his assignment to the Regents, (*Hendrie*, 98 U.S. at 549), and because the Regents were prohibited from assigning rights in the '515 patent by operation of 35 U.S.C. § 202(c)(7), (App. pp. 78a-79a), Buckberg could only acquire title in the '515 patent by complying with the statutes enacted by Congress for the disposition of rights in subject inventions. As *Crown* makes clear, compliance with the conditions specified by the Bayh-Dole Act and its implementing regulations are conditions precedent to an acquisition of title under the Act. *Crown*, 261 U.S. 24 at 40 (1923). In this case, Dr. Buckberg's admitted failure to comply with the conditions set forth by the agency under the mandates of the Bayh-Dole Act, precludes his acquisition of title in the '515 patent as a matter of law.

Upon the Regents' abandonment and submission of the case to the NIH for final disposition, the provisions specified in 35 U.S.C. §§ 202(c)(7), (App. pp. 78-79a), and 202(d), (App. 79a-80a), applied to the disposition of rights in the '404 application:

> If the contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.
> *Id.* (*Emphasis added*).

Among the regulations promulgated under the Act is 37 C.F.R. § 401.9, which states:

> Agencies which allow employee/inventor of the contractor to retain rights to a subject invention made after a funding agreement with a small business or nonprofit organization, as authorized by 35 U.S.C. § 202(d), **will impose upon the inventor** at least those conditions that would apply to a small business contractor under paragraphs (d)(1) and (3); (f)(4); (h); (i); and (j) of the clause at § 401.14(a)." 37 C.F.R. § 401.9. (52 FR 8552) (March 1987) (*emphasis added*) (App. p. 83a).

Of these regulations, 37 C.F.R. § 401.14(f)(1), (App. p. 89a), requires Dr. Buckberg to execute a confirmatory license in the Government to protect the Government's interest in the subject invention:

> (f) Contractor Action to Protect the Government's Interest.
> (1) The Contractor agrees to execute or to have executed and promptly deliver to the *Federal agency* all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the *contractor* elects to retain title, and (ii) convey title to the *Federal agency* when requested under paragraph (d) above and to enable the Government to obtain patent protection throughout the world in that subject invention. 37 C.F.R. § 401.14(f)(1)(emphasis added, italics in original). (App. p. 89a).

In accordance with 37 C.F.R. §§ 401.9, (App. p. 83a), and 401.14(f)(1), (App. p. 89a), Dr. Windom's determination

of patent rights expressly conditioned Dr. Buckberg's acquisition of rights in the '404 patent application on Dr. Buckberg's execution and timely delivery of a confirmatory license to the United States Government, which license Dr. Windom provided as an enclosure to his agency's determination of patent rights. (App. p. 71a). The admission of record in this case conclusively established that Dr. Buckberg never executed the required confirmatory license and thus failed to meet the conditions precedent to his acquisition of rights in the '404 patent application.

## 2. CONGRESSIONAL INTENT

If allowed to stand, the Federal Circuit's decision would thwart Congressional policy. Congressional intent behind the Bayh-Dole Act is expressed at 35 U.S.C. § 200. Among the purposes of the Act are ensuring that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions and to minimize the costs of administering policies in this area. 35 U.S.C. § 200. (App. p. 73a).

If permitted to stand, the decision of the Federal Circuit would completely eviscerate these provisions from the statutory scheme enacted by Congress, creating a precedent for institutions and inventors to disregard the statutory formalities in disposition of funded inventions and proceed with ad hoc business transactions involving federally funded inventions. Inventors similarly situated to Dr. Buckberg would be able to avoid any possible obligations or responsibilities under the Act by simply disregarding any restrictions imposed by the Government in its contracts. The invitation for similarly situated inventors is particularly inviting in an environment where the Government has yet to exercise its march in rights as provided under 35 U.S.C. § 203. (App. pp. 81a-82a). Such

an ad hoc approach would lead to even more disparity in the disposition of federally funded inventions rather than a uniform policy in the public interest.

The District Court's finding that the Bayh-Dole Act was not intended to create an "additional defense to patent infringers," implicitly affirmed by the Federal Circuit (App. p. 32a) is entirely misplaced because Congress enacted the Bayh-Dole Act to provide uniform procedures applicable to all Federal Agencies to protect the Government's interests in patents and to specify uniform requirements and conditions under which an inventor, such as Dr. Buckberg, may acquire title to subject inventions. 35 U.S.C. § 202(c)(7), (App. 78a-79a), and (d) (App. 79a-80a). Contrary to the decisions in these courts, the Patent Act already provides the requisite "defense to would be infringers," by virtue of Congress' explicit requirement that only "patentees" within the meaning of 35 U.S.C. § 100(d), (App. p. 72a), have any cognizable claim under 35 U.S.C. § 281. (App. p. 83a). The Bayh-Dole Act affects who is the owner of a patent covering a federally funded invention, thus, its implications must be considered in determining whether Article III, (App. p. 72a), standing has been achieved. This does not mean the Act creates a defense, but rather is a part of the web of statutory law that must be considered in determining rights in such inventions and patents.

In reaching the legal conclusion that Dr. Buckberg owned the '515 patent, the Federal Circuit and the District Court erroneously construed the issue as one of Government divestiture rather than one of acquisition of title. (App. pp. 7a-8a, 30a-32a). However, because Dr. Buckberg had no ownership interest in the '404 application by virtue of his assignment to the Regents, he possessed no rights subject to divestment by Government action and no standing to enforce the '515 patent. *Gayler et al v. Wilder*, 51 U.S. 477, 494 (1850). This was the conclusion *properly* reached by the

United States District Court for the Southern District of New York in *T.M. Patents v. IBM*, 121 F. Supp. 2d 349, 369 (S.D.N.Y. 2000), and the conclusion that the Court should adopt upon reaching the merits of this case after granting the instant petition.

While *Campbell Plastics* dealt with a situation where the Government exercised its discretion to divest a contractor of an ownership interest in the subject patent, a situation not presented in this case, it is instructive as to the effect of Dr. Buckberg's failure to execute the confirmatory license in the United States Government. As was the case in *Campbell Plastics*, the terms of Dr. Windom's determination of patent rights were clear -- Dr. Buckberg was required to execute the confirmatory license in the United States Government in order for him obtain legal title in the invention. (App. pp. 71a, 7a-8a, 30a-32a). "[A] plain-meaning interpretation of the contract is buttressed by the policy considerations behind the Bayh-Dole..." Act. *Campbell Plastics v. Brownlee*, 389 F.3d 1243 (Fed. Cir. 2004). Moreover, as had been the case in *Campbell Plastics*, Dr. Buckberg was also provided the form of the license he was required to execute to be in compliance with the Government's determination of patent rights. (App. pp. 71a, 5a). Thus, because he failed to satisfy the conditions precedent to obtaining title in the '404 application, Dr. Buckberg does not possess title in the '515 patent and, therefore, is not a patentee with standing to bring suit under 35 U.S.C. § 281.

## 3. CIRCUIT CONFLICTS

The petition should also be granted to resolve conflicts presented by the Federal Circuit's decision with those of other Circuit Courts of Appeal. In the first instance, by virtue of the restrictions imposed under 35 U.S.C. 202(c)(7), (App. pp. 78a-79a), the Regents did not have actual authority to assign the rights to Buckberg without

obtaining the permission of the Government agency. There is no record of any authorization other than the 1987 determination of patent rights, an agency ruling that was never adhered to or administratively challenged by Buckberg. There was also no apparent authority, because the assignment to Buckberg itself referenced the unchallenged determination and confirmation that Buckberg had to comply before he could obtain title. (App. p. 71a). With no actual or apparent authority and in contravention of the clear statutory prohibition of § 202(c)(7), (App. pp. 78a-79a), the Federal Circuit nonetheless held that the Regents' assignment was and remains valid. (App. p. 8a).

According to decisions of the Court of Appeals for the Second Circuit and the Court of Appeals for the District of Columbia in analogous cases, restrictions on the acquisition of ownership rights requiring agency approval or other approvals required as conditions precedent under statutes preclude the acquisition of such rights where such approval is not obtained. *See*, *Havana Club Holding S.A. v. Galleon S.A.*, 52 USPQ2d 1609 (2nd Cir. 2000) (Trademark assignment void where approval required under Cuban embargo were lacking); *see also*, *Nursing Ctr of Buckingham & Hamp. v. Shalala*, 990 F.2d 645 (D.C. Cir. 1993) (Finding merger contract unenforceable to confer ownership status under 42 U.S.C. § 1395x(v)(1)(o) in time to satisfy statutory deadline because it remained subject to shareholder approval under its express terms and under statute). Accordingly, the petition should be granted to resolve these conflicts and bring the Federal Circuit into compliance with the precedents of this Court and the Congressional purposes behind its enactment of the Bayh-Dole Act.

The Federal Circuit's decision is also in conflict with that of the Eleventh Circuit Court of Appeals. In effect, the decision of the Federal Circuit abrogated an agency determination which was committed to the discretion of the

agency and gave Plaintiff title that the Regents were powerless to assign. *Southern Research Institute v. Griffin Corp.*, 938 F.2d 1249, 1254 (11th Cir. 1991). The Federal Circuit mistakenly concluded that some Government activity was necessary to divest Dr. Buckberg of title to invalidate the assignment. However, by operation of § 202(c)(7), (App. pp. 78a-79a), the Regents had no authority to transfer title to Buckberg, absent some authorization from the NIH to do so. Thus, government inaction is not a ground for upholding a valid assignment but rather precludes the existence of a valid assignment.

The prohibition against unauthorized transfers exists as a matter of the statutory law independent of NIH's march in rights under § 203 of the Bayh-Dole Act. (App. pp. 81a-82a). What the NIH did or did not do to recover title is "not the point, since the provisions of the legislation governing the Contract control." *FilmTec v. Hydranautics*, 982 F.2d 1546, 1553 (Fed. Cir. 1992). It is hornbook law that the purchaser takes only such title as the seller had or had power to transfer. Here, the Regents had no power to transfer any title to Dr. Buckberg, because neither the Regents nor Dr. Buckberg obtained the authorization mandated by the statute, its implementing regulations, or the determination of patent rights issued by the NIH.

## X. CONCLUSION

Because the Petitioners are aggrieved by the erroneous statutory construction of the Bayh-Dole Act rendered by the District Court and Federal Circuit, and because the proper interpretation of the Bayh-Dole act is of great significance in the disposition of rights in federally funded inventions, thereby impacting taxpayers, research institutions, inventors, businesses seeking rights or licenses in such inventions and the competitors of such businesses, this case presents an important Federal Question on statutory

patent law for this Court to answer. The Court should answer clarifying that the statute cannot be disregarded in the disposition of federally funded inventions and the Courts are not free to modify or overturn requirements that are left to agency discretion. Therefore, Petitioners respectfully submit that the petition should be granted.

Respectfully submitted,

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DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

**ENTERED: APRIL 3, 2007**

United States Court of Appeals for the Federal Circuit

2006-1307

CENTRAL ADMIXTURE PHARMACY SERVICES, INC. and DR. GERALD R. BUCKBERG,

Plaintiffs-Appellees,

v.

ADVANCED CARDIAC SOLUTIONS, P.C. and CHARLES WALL,

Defendants-Appellants.

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DECIDED: April 3, 2007

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Before SCHALL, GAJARSA, and PROST, Circuit Judges.

GAJARSA, Circuit Judge.

In this patent infringement case, defendants Advanced Cardiac Solutions and Charles Wall (collectively "ACS") appeal from several summary judgment orders issued by the United States District Court for the Northern District of Alabama. The district court found ACS liable to plaintiffs Central Admixture Pharmacy Services ("CAPS") and Dr. Gerald Buckberg for willful infringement of U.S. Patent No. 4,988,515 ("the '515 patent"), and dismissed ACS's counterclaims of false marking and false

advertisement. Because the certificate of correction CAPS obtained from the U.S. Patent and Trademark Office ("PTO") to alter the asserted claims of the '515 patent is invalid, we vacate the finding of infringement and remand for a redetermination of infringement under the patent's original, uncorrected claims. We affirm the district court's summary judgment findings that the patent is not invalid and that CAPS did not commit false marking or false advertisement, as well as the court's procedural rulings with respect to ACS's defenses of inequitable conduct and patent misuse.

## I. BACKGROUND

### A. The Technology and Patent

The patent at issue claims a chemical solution used during heart surgery. If blood supply to the heart is interrupted during surgery, lack of fresh blood ("ischemia") will, untreated, cause cardiac tissue to die. '515 patent col.1 ll.11-22. The patented solution contains glucose and amino acids to nourish the heart tissue even without a continuous supply of blood, allowing surgeons to operate on the heart for longer periods of time.

The patent has claims directed to the solution and to methods of treatment using the solution. For the purposes of the issues we reach on this appeal, Claim 1 is representative. That claim initially read:

> In an amino acid enriched cardioplegic solution for use in treating human hearts to prevent or reverse heart muscle damage due to ischemia, said cardioplegic solution having a calcium ion concentration, a metabolizable substrate concentration and an osmolarity, wherein the improvement comprises:
>
> > maintaining said calcium ion concentration of said cardioplegic solution at a lowered level of between about 50-300 umol;

> maintaining said concentration of metabolizable substrate in said cardioplegic solution between about 400-1000 mg % wherein said metabolizable substrate is selected from the group consisting of glucose, fructose, a salt of malic acid, a salt of succinic acid and a salt of pyruvic acid; and
>
> maintaining said osmolarity of said cardioplegic solution at an increased level of between about 400-500 mOsmol.

'515 patent col.8 l.56 to col.9 l.5 (emphasis added).

B. The Certificate of Correction

On December 15, 1999, CAPS applied, pursuant to 35 U.S.C. § 255, for a certificate of correction to replace all instances of the word "osmolarity" in the '515 patent with the word "osmolality."

Section 255 provides:

> Whenever a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

On January 30, 2001, after the complaint in this lawsuit was filed, the PTO issued the requested certificate. The two terms, which each describe the concentration of a

chemical solution contributing to that solution's osmotic pressure, are related but subtly different in meaning. "Osmolarity" refers to the amount of solute (dissolved chemical) per liter of total solution. At the concentrations involved in this case, osmolarity is measured in milliosmoles per liter (mOsmol/L). In contrast, "osmolality" refers to the amount of solute per kilogram of solvent. It is measured in milliosmoles per kilogram (mOsmol/kg). Osmolality can be more-or-less directly measured and calculated using a device called an osmometer, which computes osmolality from the depression of the solution's freezing point. Osmolarity is derived from the osmolality figure.

As highlighted above, the asserted patent claims initially required the solution to have an "osmolarity . . . of between about 400-500 mOsmol," but after the certificate issued, the claims required an "osmolality . . . of between about 400-500 mOsmol."[1] (emphasis added). For the solutions at issue here, the numerical figure for osmolarity will be less than the figure for osmolality by about one or two percent.[2] The result of this change is to cause the claimed concentration range to shift slightly downwards, covering less-concentrated solutions near the low end of the claimed range and ceasing to cover more-concentrated solutions near the high end. All of the allegedly infringing solutions have concentrations near the low end of the claimed range. Because of the change in the range, it is more likely that the accused solutions infringe the corrected

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[1] Both before and after correction, the claims indicated units of "mOsmol," (a measurement of quantity, not concentration) rather than "mOsmol/L" (the units of osmolarity) or "mOsmol/kg" (osmolality). Under either the "osmolarity" or "osmolality" version of the claim, the choice of unit is technically incorrect. The correct denominator depends on which of the two terms is used.

[2] As an example, CAPS provides a chart in its brief that converts between the measured osmolality and computed osmolarity of various accused solutions. The solution described in the chart's top-left cell has an osmolality of 391 mOsmol/kg and an osmolarity of 382 mOsmol/L.

claims, while they may not have infringed the original claims.

C. Dr. Buckberg's Dealings with UC and NIH

The research that led to the '515 patent was conducted under a grant awarded by the National Institutes of Health ("NIH") to Dr. Buckberg's employer, the University of California ("UC"). '515 patent col.1 ll.23-25. The government therefore has certain rights with respect to the patent under the Bayh-Dole Act, 35 U.S.C. §§ 200-212, including the right to be notified of the invention, id. § 202(c)(1), to obtain patents in foreign countries where the inventor does not pursue patent applications, id. § 202(c)(3), a royalty-free nonexclusive license, id. § 202(c)(4), and the ability under certain circumstances to "march-in" and compel the patentee to grant a license to a third party, id. § 203.

During patent prosecution, Dr. Buckberg designated UC as his assignee. On February 12, 1987, UC communicated to NIH its intent to abandon its interest in the pending application. One month later, Dr. Buckberg wrote to NIH to request that it waive patent rights in the application so that he could pursue the application in his personal capacity. See 35 U.S.C. § 202(d) (allowing agencies to grant such requests). NIH granted that waiver on September 23, 1987, on the condition that "the inventor shall grant to the Government of the United States a nonexclusive, irrevocable, royalty-free license to use the invention for governmental purposes. . . . This determination will become effective upon receipt of the executed copy [of the license]." Dr. Buckberg made an admission under Fed. R. Civ. P. 36 that he never executed the requested license.[3] The patent issued on January 29, 1991. On June 24, 1991, UC assigned

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[3] However, the patent's written description recognizes, as required by 35 U.S.C. § 202(c)(6), that the invention was made with support from NIH funding and that "[t]he Government has certain rights in this invention." '515 patent co. 1, ll.23-26.

its interest in the '515 patent to Dr. Buckberg. The same day, Dr. Buckberg exclusively licensed the patent to CAPS.

D. Litigation History

On August 31, 2000, CAPS filed this infringement suit. Dr. Buckberg later joined as a plaintiff. In an order dated January 13, 2006, the district court disposed of most of the issues in the case. It found that the plaintiffs had standing to bring this suit, granted summary judgment to the plaintiffs that the patent was not invalid and that the plaintiffs had not committed false marking or false advertising, and dismissed the defendants' inequitable conduct defense on the pleadings. It also granted to the plaintiffs conditional summary judgment of infringement and willfulness for actions occurring after the issuance of the certificate of correction, contingent upon the certificate being found valid. The district court later determined that the certificate was valid as a matter of law. The plaintiffs then withdrew their claims of infringement for acts prior to the issuance of the certificate, making the district court's infringement and willfulness judgments final as to all acts of infringement still alleged by the plaintiffs. ACS timely appealed to this court.

II. DISCUSSION

A. Standing

ACS argues that CAPS lacks standing to bring this action because, as a result of Dr. Buckberg's failure to execute the license required by NIH, neither CAPS nor Dr. Buckberg have rights to the '515 patent. If ACS is correct, this action must be dismissed since only the patent owner or the holder of all substantial rights under the patent may sue for infringement. See Propat Int'l Corp. v. RPost, Inc., 473 F.3d 1187, 1189-93 (Fed. Cir. 2007); Fieldturf, Inc. v. Sw. Recreational Indus., 357 F.3d 1266, 1268-70 (Fed. Cir. 2004); Speedplay, Inc. v. Bebop, Inc., 211 F.3d 1245, 1249-52 (Fed. Cir. 2000); Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1551-52 (Fed. Cir. 1995) (en banc).

As an initial matter, Dr. Buckberg admitted pursuant to Fed. R. Civ. P. 36 that he did not execute the license to NIH. He later sought to retract that admission, but the district court refused to allow him to do so. That refusal was not an abuse of discretion, so the fact that Dr. Buckberg did not execute the license is for the purposes of this case "conclusively established." Fed. R. Civ. P. 36(b).

We discussed the consequences of a patentee's failure to comply with the requirements of the Bayh-Dole Act in Campbell Plastics Engineering & Manufacturing, Inc. v. Brownlee, 389 F.3d 1243 (Fed. Cir. 2004). In that case, an Army contractor working under a cost-plus-fixed-fee contract developed an invention during the course of its work. Id. at 1244. The contract incorporated by reference regulation 48 C.F.R. § 52.227-11,[4] which requires that a contractor disclose to the government inventions made pursuant to the contract. Id. The contractor in Campbell Plastics did not disclose that it had developed patentable subject matter, id. at 1245, but obtained a patent on the invention, id. at 1246. An Administrative Contract Officer with the Army demanded title to the invention, and the Armed Services Board of Contract Appeals ("ASBCA") affirmed. Id. at 1244. We affirmed the ASBCA, finding that the contractor's failure to disclose the invention as provided in the contract "afforded the government the opportunity to take title to its patent." Id. at 1249. The government chose to exercise its right pursuant to the regulations, and as a result, title to the patent was forfeited to the government. Id. at 1250.

Critically, Campbell Plastics holds that a Bayh-Dole violation grants the government discretionary authority to take title. Id. at 1250 (regulation "vests discretion in the

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[4] The regulation at issue in Campbell Plastics is in relevant part substantially the same as 37 C.F.R. § 401.14, which was incorporated into the grant agreement between UC and NIH. Compare 48 C.F.R. §52.227-11 with 37 C.F.R. § 401.14.

government in determining whether to invoke forfeiture when an invention has not been correctly disclosed to it." (emphasis added)). When a violation occurs, the government can choose to take action; thus, title to the patent may be voidable. However, it is not void: title remains with the named inventors or their assignees. Nothing in the statute, regulations, or our caselaw indicates that title is automatically forfeited. The government must take an affirmative action to establish its title and invoke forfeiture. The defendants here have no basis to challenge the government's discretion in not invoking forfeiture.

It may be that Dr. Buckberg's failure to execute the required license enables NIH to exercise its discretion to void his title in the '515 patent—a question we assuredly do not decide today. However, NIH has shown no interest in pursuing the matter. Absent any action by NIH, Dr. Buckberg retains title to the patent and his exclusive license to CAPS is valid. The two plaintiffs together own all present rights in the '515 patent, providing them standing to bring the action. Since the district court's infringement judgment is final as to all issues except for a determination of damages, we have jurisdiction under 28 U.S.C. § 1292(c)(2). See Mendenhall v. Barber-Greene Co., 26 F.3d 1573, 1581 (Fed. Cir. 1994).

B. The Certificate of Correction

A patentee who has made "a mistake of a clerical or typographical nature, or of minor character" may apply to the PTO for a "certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination." 35 U.S.C. § 255. We have previously interpreted this statutory provision in Superior Fireplace Co. v. Majestic Products Co., 270 F.3d 1358 (Fed. Cir. 2001). Superior Fireplace held that if a certificate of correction broadens a claim, it is only valid if it corrects a "clerical or typographical" error that would have been clearly evident to one of skill in the art reading the intrinsic evidence. Id. at 1373 ("[W]e interpret § 255 to

require that a broadening correction of a clerical or typographical error be allowed only where it is clearly evident from the specification, drawings, and prosecution history how the error should appropriately be corrected."); id. at 1375 ("A mistake that, if corrected, would broaden the scope of a claim . . . cannot be a mistake of 'minor character.'"). Since the result is to invalidate a certificate of correction which is part of a duly issued patent, the party seeking invalidation must meet "the clear and convincing standard of persuasion." Id. at 1367.

Invalidating a certificate of correction for impermissible broadening therefore requires proof of two elements: (1) the corrected claims are broader than the original claims; and (2) the presence of the clerical or typographical error, or how to correct that error, is not clearly evident to one of skill in the art. The first element poses a question of law, since the correct scope and meaning of a claim is an issue for the court to decide. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996); see also Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998) (en banc). To answer the question of whether a claim has been broadened through correction requires interpreting the old and new versions of that claim, and then determining whether the new version covers territory the old one did not. This same inquiry has been treated as a question of law in § 251 reissue cases, and should be treated as such in the § 255 context as well. See MBO Labs., Inc. v. Becton, Dickinson & Co., 474 F.3d 1323, 1332 (Fed. Cir. Jan. 24, 2007); In re Clement, 131 F.3d 1464, 1468 (Fed. Cir. 1997) (deciding as a matter of law "whether and in what aspect the reissue claims are broader than the patent claims").We find that these claims were broadened by the certificate of correction, since the claims as corrected cover less-concentrated solutions which would not be covered under the original claims.

The second element, whether the error and its correction would both be clearly evident to one of skill in the art, has been treated as a factual question. See ArthroCare Corp. v. Smith & Nephew, Inc., 406 F.3d 1365, 1374-75 (Fed. Cir. 2005) (reviewing jury verdict for substantial evidence); Superior Fireplace, 270 F.3d at 1373 (reviewing district court's summary judgment for "a genuine issue"). ACS moved for judgment that the certificate of correction was invalid, but the district court ruled as a matter of law that the certificate was valid. Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 54(c).

Superior Fireplace posits three categories into which an error might fall. The first category involves "mistakes [that] are immediately apparent and leave no doubt as to what the mistake is." Id. at 1370. This category includes "misspellings that leave no doubt as to the word which was intended; 'frane' instead of 'frame,' for example." Id. This category also extends to clerical errors in which the patentee attempts to change every instance of a particular claim term in prosecution but misses one, leaving a claim that, on its face, is nonsensical in light of the specification. In such cases, one of skill in the art would know from the prosecution history that the patentee had missed one term and would know that the proper correction would be to change that term as well. ArthroCare, 406 F.3d at 1374-75.

Since an error of the first category makes its own correction known to one of skill in the art, those errors do not raise serious public notice problems and can properly be corrected via a § 255 certificate.

> In contrast, a second category includes those typographical mistakes not apparent to the reader at all; for example, a mistake resulting in another word that is spelled correctly and that reads logically in the

> context of the sentence. A third category of mistakes includes those where it is apparent that a mistake has been made, but it is unclear what the mistake is.

Superior Fireplace, 270 F.3d at 1370. "It is not evident to the reader of the public record how to appropriately correct mistakes of the second and third categories," id., so those categories of error cannot be repaired via a certificate of correction if the effect would be to broaden the claim.

The undisputed facts demonstrate that the error here is one of the second category. The word 'osmolarity' is indeed "spelled correctly and reads logically in the context of the sentence." Id. All solutions of the type described have a calculable osmolarity, and to one of skill in the art, a concentration of about 400-500 mOsmol/L is not a manifestly erroneous one.[5] The patentee specified a particular unit of measure for his claim. That unit measures the appropriate property (chemical concentration) and the claimed range is, as demonstrated by the written description, generally effective for the stated purpose. The fact that the unit of measure that the patentee indicated is not the most conventional or convenient is of limited significance.[6] Claims mean precisely what they say. Cf. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention." (emphasis

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[5] The result might be different if the patentee's choice of unit resulted in a clearly incorrect claim—"fifty miles" instead of "fifty meters," for instance. Here, though, the difference between an osmolarity of 400 mOsmol/L and an osmolality of 400 mOsmol/kg is very slight.

[6] CAPS' technical expert testified that because osmolarity cannot be measured as directly as osmolality, one of skill in the art "could discern" that a mistake had occurred. However, *Superior Fireplace* does not allow the mere possibility that one of skill in the art might perceive an error to support a broadening correction. Instead, it must be "*clearly evident* from the specification, drawings, and prosecution history how the error should appropriately be corrected." 270 F.3d at 1373 (emphasis added).

added)) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

Since the error corrected here was not clearly evident to one of skill in the art and the result of its correction was to broaden the claims, ACS should be granted summary judgment that the certificate of correction is not valid. The patent therefore continues to read as it did prior to the issuance of the certificate. See Superior Fireplace, 270 F.3d at 1367 ("[I]nvalidation of the certificate of correction result[s] in [the] uncorrected claim . . . being restored.").

Because the district court's summary judgments of infringement and willfulness were both explicitly contingent on the validity of the certificate of correction, both of those judgments are vacated. On remand, the infringement inquiry should proceed under the original "osmolarity" versions of the claims.[7]

C. Claim Construction

The district court construed the phrase "osmolality . . . of between about 400-500 mOsmol" in the corrected claims to allow for an osmolality between 385-515 mOsmol/kg. Since that construction interprets language that is not validly part of the claims, it cannot stand exactly as issued. However, the correct construction of the originally issued claims is basically the same, except for the substitution of units: "osmolarity . . . of between about 400-500 mOsmol" encompasses osmolarities as low as 385 mOsmol/L. Rather than basing this broadening of the enumerated range on the alleged interchangeability of the terms "osmolarity" and "osmolality," as the district court did, we base it on the presence of the word "about" in the claim.

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[7] Since the findings of infringement and willfulness are vacated on the ground that the certificate of correction is invalid, we do not reach ACS's arguments relating to CAPS' infringement tests of the accused products, secondary infringement, prosecution history estoppel, or the opinion of counsel ACS alleges it relied on to defeat willfulness.

> The use of the word "about[]" avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technological and stylistic context. We thus consider how the term was used in the patent specification, the prosecution history, and other claims. It is appropriate to consider the effects of varying that parameter, for the inventor's intended meaning is relevant. Extrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter.

Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1326 (Fed. Cir. 2007) (ellipses omitted) (quoting Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995)). Here, the intrinsic evidence indicates that the overall osmolarity of the solution is crucial to its effectiveness, and that osmolarities over 400 mOsmol/L are most consistently effective. See '515 patent Figs. 2-3. However, that evidence also shows that osmolarities below 400 mOsmol/L are effective. The patent's Figure 2 details the result of an experiment measuring the effect of solution osmolarity on systolic shortening, an indicator of the health of cardiac tissue. The figure makes clear that as osmolarity increases from about 360 mOsmol/L to about 480 mOsmol/L, systolic shortening improves. It includes a trend line that extrapolates a linear relationship between osmolarity and shortening; that line crosses the figure's x-axis near to 385 mOsmol/L, indicating that the break-even point for effectiveness is found close to that concentration. Since the intrinsic evidence indicates that the solution begins to be effective near a concentration of 385 mOsmol/L, the word "about" extends the range of the claim downward to that point.

ACS also argues that the district court erred by failing to construe the term "maintaining" in Claims 7-12. The district court found that ACS waived any argument with respect to this term by failing to raise it during the claim construction phase. We agree. Since ACS has not preserved

this argument before the district court, we do not reach it here.

Finally, ACS suggests that the patent's Claim 13 and its dependent claims are invalid for indefiniteness, since they describe a solution that is "adapted to be diluted." We do not read that phrase as possessing any significant ambiguity, much less intractable ambiguity making the claim "not amenable to construction," which is the requirement to demonstrate indefiniteness. Aero Prods., Inc. v. Intex Rec. Corp., 466 F.3d 1000, 1016 (Fed. Cir. 2006).

D. Inequitable Conduct

The district court dismissed ACS's defense that the patent was unenforceable due to inequitable conduct because ACS failed to plead that conduct with particularity. Whether inequitable conduct has been adequately pled is a procedural matter, but since it bears on an issue that "pertains to or is unique to patent law," we will apply our own law to the question of whether the pleadings were adequate. See Intel Corp. v. Commonwealth Sci. & Indus. Research Org., 455 F.3d 1364, 1369 (Fed. Cir. 2006).

We have held that "inequitable conduct, while a broader concept than fraud, must be pled with particularity." Ferguson Beauregard/Logic Controls, Inc. v. Mega Sys., LLC, 350 F.3d 1327, 1344 (Fed. Cir. 2003). ACS pleaded inequitable conduct by alleging only that "during prosecution of the '515 patent, the patentee failed to disclose all of the relevant prior art known to it" and that "by manipulation of various measurements and units, the patentee sought to mislead the Patent and Trademark Office regarding the relationship between the claimed invention and the prior art." Defendants' Third Amended Answer (N.D. Ala. Mar. 16, 2005). This pleading lacks the requisite particularity. It does not identify what relevant and undisclosed prior art was known to the patentee, what "measurements and units" were manipulated, or how that manipulation was meant to mislead

the PTO.[8] The pleading thus fails to provide the required particularity to give notice to the other party of the facts on which the defense is premised, and it was properly dismissed by the district court.

ACS sought to amend this element of its pleadings, but the district court refused to grant it leave to amend. ACS appeals the denial. We apply the procedural law of the Eleventh Circuit, which reviews denials of leave to amend an answer for abuse of discretion. Hall v. Aetna Cas. & Sur. Co., 617 F.2d 1108, 1110 (11th Cir. 1980). No such abuse is present here. ACS's attempt to amend its pleadings came on December 27, 2004, over three years after the close of discovery. The district court correctly noted that ACS's amended answer would "require the parties to conduct new discovery, including entirely new expert discovery, thereby essentially reopening a case that has been pending since 2000." Order Striking Answer, Cent. Admixture Pharm. Servs., Inc. v. Advanced Cardiac Solutions, P.C., No. 00-CV-2430 (N.D. Ala. Mar. 3, 2005). The district court's authority to manage discovery is broad enough to place this ruling within its sound discretion.

Since ACS did not properly plead inequitable conduct and cannot now amend its answer to do so, inequitable conduct is not part of this case on remand.

E. Validity

The district court's summary judgment of no invalidity disposed of several arguments by ACS. ACS has appealed on only two grounds: it argues that the claims are indefinite and that the asserted claims are barred under 35 U.S.C. § 102(b) by certain clinical trials allegedly performed by Dr. Buckberg more than one year before the patent application was filed on August 21, 1985. We addressed and

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[8] This is not to suggest that the PTO must actually rely on a prosecution statement or omission in order for that statement to be material in the context of inequitable conduct. See C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1365 (Fed. Cir. 1998).

rejected the indefiniteness argument in Part II.C., supra. The district court's § 102(b) finding would be affirmed whether the claims read "osmolarity" or "osmolality," so we resolve this issue now rather than remanding it.

The Supreme Court has held that "[t]he plain language of [Federal] Rule [of Civil Procedure] 56(c) mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). The only evidence ACS presents to demonstrate a bar under § 102(b) is a scientific article co-authored by Dr. Buckberg describing a study of his cardioplegic solution conducted on patients between May 1984 and April 1985. Part of that period—between an unspecified day in May 1984 and August 20, 1984—falls more than one year before the application for patent. The article is totally nonspecific, though, as to what type of surgical activity occurred before August 21, 1984, and ACS has presented no other evidence whatsoever that any surgeries using the claimed invention actually took place before that critical date. The alleged infringer bears "the burden of proving invalidity by clear and convincing evidence." U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1564 (Fed. Cir. 1997); see also Abbott Labs. v. Baxter Pharm. Prods., Inc., 471 F.3d 1363, 1367 (Fed. Cir. 2006); Typeright Keyboard Corp. v. Microsoft Corp., 374 F.3d 1151, 1157 (Fed. Cir. 2004). On this very sketchy record, no reasonable jury could find by clear and convincing evidence that the described surgeries using the claimed invention occurred prior to the critical date. Since ACS has failed to meet its burden of coming forward with evidence to create a genuine dispute of fact on this issue, we affirm the summary judgment without reaching CAPS' argument that any surgeries performed during the study were experimental in nature.

We have rejected all of ACS's arguments on appeal that the asserted claims are invalid. ACS has not preserved any of its other validity arguments, so on remand validity is not at issue.

F. ACS's counterclaims

The district court granted summary judgment to CAPS on ACS's counterclaims for false marking and false advertisement. There is no error in either of these determinations, and we affirm the district court. It also refused to allow ACS to amend its answer to introduce a counterclaim for patent misuse. For the reasons discussed in Part II.D., supra, the district court did not abuse its discretion by prohibiting that amendment.

## III. CONCLUSION

We reverse the district court's finding that the certificate of correction applied to the '515 patent is valid. The district court's summary judgment of infringement is therefore vacated. We affirm the district court's summary judgments that the patent is not invalid and that there is no liability for false marking or false advertisement, its decision not to allow ACS to file an amended answer raising patent misuse or alter its pleadings with respect to inequitable conduct, and its dismissal of ACS's inequitable conduct defense. On remand, CAPS may pursue its allegations of infringement of the uncorrected "osmolarity" version of the '515 patent claims.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, and REMANDED

No costs.

NOTE: This order is nonprecedential

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

**[ENTERED: MAY 16, 2007]**

**ORDER**

Before Schall, Circuit Judge, Gajarsa, Circuit Judge, and Prost, Circuit Judge.

A petition for rehearing having been filed by the Appellant,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED.

The mandate of the court will issue on May 23, 2007.

FOR THE COURT,
/s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 05/16/2007
cc: Robert J. Veal
Brett Johnston Williamson

CENTRAL ADMIXTURE V. ADVANCED CARDIA,
2006-1307
(DCT-00-CV-2430)

[CORRECTED] MEMORANDUM OF OPINION NORTHERN DISTRICT OF ALABAMA FILED JANUARY 13, 2006

United States District Court,
N.D. Alabama, Southern Division.

CENTRAL ADMIXTURE PHARMACY SERVICES, INC., and
Gerald Buckberg,
Plaintiffs,
v. No. CV-00-2430-VEH.

ADVANCED CARDIAC SOLUTIONS, P.C., and
Charles Wall,
Defendants.

Jan. 13, 2006.

[CORRECTED] MEMORANDUM OF OPINION

HOPKINS, J.

Before the court are four motions for summary judgment, filed by the plaintiffs, Central Admixture Pharmacy Services, Inc. ("CAPS"), and Gerald Buckberg; and two motions for summary judgment and one motion for judgment on the pleadings, filed by the defendants, Advanced Cardiac Solutions, P.C. ("ACS"), and Charles Wall.

The instant cause is a civil action for the infringement of U.S. Patent Number 4,988,515 (the " '515 patent"). The plaintiffs are, Dr. Gerald Buckberg, the inventor and alleged owner of the patent, and CAPS, the exclusive licensee of the

patented invention. In their complaint, the plaintiffs assert a cause of action under federal patent law, 35 U.S. C. §§ 281, et seq., against the defendants ACS and Charles Wall for infringement of the '515 patent by producing, commercially marketing, and selling directly infringing products, and by inducing others to infringe the patent by producing infringing products.

In their Third Amended Answer and Counterclaim, the defendants assert several defenses to the plaintiffs' patent infringement claim as well as three counterclaims of their own. In Counterclaim I, the defendants seek a declaration that the '515 patent is unenforceable and, alternatively, that the defendants did not infringe the patent. In Counterclaim II, the defendants assert a cause of action under 35 U.S.C.A. § 292 for false marking. In Counterclaim III, the defendants assert a cause of action for false advertising under the Lanham Act, 15 U.S.C.A. § 1125(a)(1)(b).

In the instant motions filed by the defendants, the defendants seek judgment on the plaintiffs' claim of infringement on three separate grounds. In the first motion (doc. 219), the defendants seek judgment on the pleadings on the ground that the plaintiffs do not have title to the patent. In the second motion (doc. 233), the defendants move for summary judgment based upon the defense that the plaintiffs engaged in inequitable conduct in the procurement of the patent. In the third motion (doc. 235), the defendants seek partial summary judgment on the ground that the plaintiffs have failed to adduce any evidence that the defendants infringed the '515 patent prior to the issuance of the Certificate of Correction.

In the instant motions for summary judgment filed by the plaintiffs, the plaintiffs seek judgment on their claim of infringement, on the defendants' three counterclaims, and on an unpled counterclaim for violations of the Sherman Anti-Trust Act. In the plaintiffs' first motion (doc. 220), they seek summary judgment on their claim of infringement and against the defendants' counterclaim for a declaration of no

infringement. In the plaintiffs' second motion (223), they seek summary judgment on the defendants' defense that the '515 patent is invalid. In the plaintiffs' third motion (doc. 226), the plaintiffs seek summary judgment on the defendants' counterclaim of false marking and false advertising under Lanham Act. In the plaintiffs' fourth motion (doc. 229), they seek summary judgment on the defendants' affirmative defense of inequitable conduct, patent misuse, and on an unpled counterclaim under the Sherman Anti-Trust Act.

These motions were opposed, fully briefed, and were taken under submission by the court on July 26, 2005.

SUMMARY OF DISPOSITION

For the reasons below, the court rules as follows:

1. The defendants' motion for judgment on the pleadings for lack of ownership of the '515 patent (doc. 219) is DENIED;

2. The plaintiffs' motion for summary judgment as to the defendants' claim of inequitable conduct and patent misuse (doc. 229) is GRANTED[1] and the defendants' motion for summary judgment on inequitable conduct (doc. 233) is DENIED;

3. The plaintiffs' motion for summary judgment as to the defendants' claim of that the '515 patent is invalid on grounds of obviousness (doc. 223) is GRANTED;

4. The plaintiffs' motion for summary judgment on its claim of infringement (doc. 220) is DENIED IN PART and GRANTED IN PART as follows: summary judgment is

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[1] Because the plaintiffs' motion for summary judgment on the defendants' unpled counterclaim of antitrust violation (doc. 229) is DENIED AS MOOT, the plaintiffs' fourth motion for summary judgment (doc. 229) is GRANTED IN PART as to defendants' defenses of inequitable conduct and patent misuse and DENIED IN PART as to the defendants' unpled antitrust counterclaim. The defendants failed to plead a counterclaim for violations of the federal antitrust laws, and the claim simply is not before the court.

granted as to whether the defendants willfully infringed the '515 patent provided that the certificate of correction is found to be valid; summary judgment is denied as to whether the certificate of correction is valid;

5. The defendants' partial motion for summary judgment of no infringement prior to the issuance of the certificate of correction (doc. 235) is DENIED;

6. The plaintiffs' motion for summary judgment on the second counterclaim of false marking and third counterclaim of false advertising (doc. 226) is GRANTED.

PROCEDURAL BACKGROUND

The plaintiff CAPS commenced this action on August 31, 2000, by filing a complaint with this court asserting a cause of action for patent infringement under federal patent law. Fact discovery in this case initially closed on August 17, 2001.

On April 30, 2002, the court conducted a Markman hearing to construe the claims of the '515 patent. On May 2, 2002, the court issued its Markman order construing the claims of the patent. On November 21, 2003, the plaintiffs filed their motions for summary judgment. On December 8, 2003, the court extended the deadline for filing dispositive motions until March 23, 2004. On March 23, 2004, the date of the dispositive motion deadline, the defendants filed two motions for summary judgment, as well as a motion to dismiss and a motion regarding claim construction. On September 1, 2004, the defendants filed an additional motion for summary judgment on the previously unraised grounds of inequitable conduct and common law fraud, along with a "supplemental" motion for summary judgment on the ground of patent invalidity.

On November 29, 2004, the court entered an order denying the defendants' motion to dismiss for lack of standing. However, the court agreed with the defendants' argument that CAPS, the exclusive licensee of the patented technology, was required to join the inventor, Dr. Gerald

Buckberg, as a plaintiff to the action to comply with statutory, as opposed to constitutional, standing requirements. On December 15, 2004, Dr. Buckberg was joined as a plaintiff in the action. On January 7, 2005, the court gave the defendants 60 days to conduct discovery on Dr. Buckberg.

Due to the additional discovery and the passage of time, on March 3, 2005, the court denied all of the parties' previously filed summary judgment motions. On May 5, 2005, the court required that new motions for summary judgment be filed by June 6, 2005. The parties filed six new motions for summary judgment on the date of the deadline. In addition, on May 23, 2005, the defendants also filed a motion for judgment on the pleadings. On July 26, 2005, the court took those summary judgment motions and the motion for judgment on the pleadings under submission. They are now before the court.

## THE TECHNOLOGY

The invention at the heart of this dispute is called a cardioplegic solution. Cardioplegic solutions are chemical solutions used during open-heart and other kinds of stop-heart surgical procedures. One type of cardioplegic solution is used to stop the heart and reduce its energy demands. While the heart is stopped, the patient is sustained on a cardiopulmonary by-pass machine, which maintains the circulation of oxygenated blood through the body. Meanwhile, another cardioplegic solution is used to protect the heart from muscle damage, called ischemia, while the heart is stopped. At the conclusion of the operation, a different cardioplegic solution is infused to start the heart beating again and to prepare the heart for the return of normal blood flow, a process called reperfusion.

## THE '515 PATENT

The invention covered by the '515 patent is described as a "cardioplegic solution." Commercially, the invention is known as a "Buckberg Solution" (hereinafter the "Invention"

or the "Buckberg Solution") and is named for the inventor, the plaintiff Dr. Buckberg. The patent involves two varieties of cardioplegic solutions: high potassium solutions, which are used initially to stop the heart's beating at the beginning a stop-heart surgical operation, and low potassium solutions, which are used to protect the heart from muscle damage during the surgery. These solutions are called "blood cardioplegic" solutions because the solutions are mixed with the patient's blood before they are infused into the patient's heart.

The '515 invention consists of an amino acid enriched cardioplegic solution with (1) a calcium ion concentration of between 50-300 umol; (2) a concentration of metabolizable substrate between about 400-1000 mg%; and (3) an osmolality of between about 400-500 mOsmol/kg.[2] Because blood usually has a calcium concentration of 1000 umol, a calcium content of 50-300 umol is considered hypocalcemic. Although the patent allows for several varieties of metabolizable substrates, the metabolizable substrate used most often appears to be glucose. A solution having a concentration of glucose between about 400- 1000 mg% would fall within the '515 patent's second criterion. Osmolality refers to the number of particles of solute per kilogram of water in the solution and is denoted by the abbreviation mOsmol/kg.[3] Because blood usually has an osmolality of approximately 280-300 mOsmol/kg, the levels of osmolality in described by the '515

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[2] The '515 patent originally provided for the invention to have an *osmolarity* of between about 400-500 mOsmol. On January 30, 2001, the United States Patent and Trademark Office issued a certificate of correction changing every instance of osmolarity in the '515 patent to osmolality. Although the question of the certificate of correction's validity is centrally disputed in this action, for purposes of providing the background of the dispute, the court refers to the '515 patent as altered by the certificate of correction.

[3] Osmolarity, by contrast, refers to the number of particles of solute per liter of solution and is denoted by the abbreviation mOsmol/L.

patent (between about 400-500 mOsmol/kg) are considered moderately hyperosmotic.

In addition, because the Buckberg Solution is an amino acid enriched solution, it contains 10-30 mmol of the amino acid aspartate and 10-30 mmol of the amino acid glutamate. The solution must have a pH of between 7.5 and 7.7. The Buckberg Solution generally contains blood, but the '515 patent covers solutions involving a "carrier" or "cardioplegic compatible diluent" other than blood as well. However, for the purposes of this action, the only relevant carrier or diluent involved is blood.

The '515 patent has three independent claims: claims 1, 7, and 13. Claim 1 has seven dependent claims (Claims 2-6, 18) and patents specific types of cardioplegic solutions. Claim 7 has five dependent claims (Claims 8-12) and patents methods for treating hearts with cardioplegic solutions. Claim 13 has four dependent claims (Claims 14-17) and patents concentrated aqueous solutions that need to be diluted to become cardioplegic solutions. As mentioned above, for purposes of this action, the concentrated aqueous solution referred to in Claim 13 will be diluted with blood to become a cardioplegic solution.

Under all three of the '515 patent's independent claims, the solution, the treatment, and the aqueous solution adapted to be diluted must contain (1) a calcium ion concentration of between 50-300 umol; (2) a concentration of metabolizable substrate between about 400-1000 mg%; and (3) an osmolality of between about 400-500 mOsmol/kg.

I.

Ownership of the '515 patent

The defendants moved for judgment on the pleadings on the ground that the plaintiffs do not own the '515 patent. The facts relevant to this motion are set out below.

A. Facts

Dr. Buckberg created the Buckberg Solution at some point between 1979 and 1985. During this period, Dr.

Buckberg was an employee of the University of California. He developed the solution while conducting research pursuant to National Institutes of Health ("NIH") research grant number HL-16292. On August 2, 1985, Dr. Buckberg conveyed his interest in the Buckberg Solution to the University of California.

On August 21, 1985, Dr. Buckberg applied for a patent on the Buckberg Solution. In the patent application, Dr. Buckberg named himself as the inventor. On December 13, 1985, the Regents of the University of California granted the United States a nonexclusive, nontransferable, irrevocable, royalty-free license to use the Buckberg Solution. (Def.Ex. E.)

On March 11, 1987, Dr. Buckberg requested a waiver of patent rights from the NIH. On September 23, 1987, the Assistant Secretary for Health, Dr. Robert E. Windom, issued a waiver of patent rights with respect to the Buckberg Solution. The waiver provided that Buckberg was "free to retain and administer the patent rights to the invention in accordance with the requirements of 37 C.F.R. § 401 .9" and that "the inventor shall grant to the government of the United States a nonexclusive, irrevocable, royalty-free license to use the invention for government purposes." (Def.Ex. G.)

In response to the defendants' requests for admissions, Dr. Buckberg admitted that he "did not execute a license to the United States Government in the invention covered by U.S. Patent 4,988,515 at any time between 1987 and 1991." (Def.Ex. I.)

On January 29, 1991, the PTO issued patent '515, which covered the Buckberg Solution. (Def.Ex. C.) The '515 patent lists Dr. Buckberg as the inventor and the Regents of the University of California as the assignees. (Id.) The '515 patent further provides that "the invention was made with Government support under Grant No. HL 16292 awarded by the National Institutes of Health. The Government has certain rights in this invention." (Id.) On June 24, 1991, the

Regents of the University of California assigned their rights to the patent to Dr. Buckberg. (Pla.Ex. FFF.)

B. Legal Standard

Judgment on the pleadings is proper when no issues of material fact exist and the movant is entitled to judgment as a matter of law. See Ortega v. Christian, 85 F.3d 1521, 1524-25 (11th Cir. 1996)[4].

C. Analysis

The defendants' motion for judgment as a matter of law is based on the argument that Dr. Buckberg failed to perfect his title to the invention due to his failure to comply with the Bayh-Dole Act, 35 U.S.C.A. §§ 200-12, the related agency regulations, and the requirements in the NIH's waiver of patent rights that Buckberg execute a license in favor of the United States.[5] (See Def. Ex. G.) With respect to the Bayh-Dole Act, the defendants argue that the Act required Dr. Buckberg to grant the United States a paid-up, irrevocable license to use the Buckberg Solution, and that, because Buckberg failed to do so, he lacks title to the '515 patent.

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[4] Because the defendants' motion is based almost entirely upon documents not included within the pleadings, the defendants' motion for the most part is a motion for summary judgment. To the extent that the defendants base their arguments on documents outside the pleadings, the court will evaluate the motion under the standard governing summary judgment set out *infra*.

[5] The defendants also move for judgment on the pleadings on the ground that the plaintiffs failed to specifically allege that Dr. Buckberg owns the '515 patent. Not only is this argument frivolous, but the defendants are estopped from making it. Earlier in the litigation, the defendants moved for dismissal on the basis that Dr. Buckberg, the patent owner, had not been joined as a plaintiff to the action. In course of advancing that argument, the defendants unequivocally asserted that "The patent is owned by Gerald Buckberg." (*See* Defs.' Mot. to Dismiss, doc. 79, at 3.) Having induced the court to order the joinder of Dr. Buckberg on the basis of that argument, the defendants now are estopped from complaining about the inadequacy of the plaintiffs' pleading with regard to Dr. Buckberg's ownership of the '515 patent.

The Bayh-Dole Act, 35 U.S.C.A. §§ 200-12, governs the patent rights of inventions made with federal assistance. For the act to apply, a party must be a contractor who enters into funding agreements with federal agencies and who reduces to practice an invention, called a subject invention, in the performance of the work under the funding agreement. Here, there is no dispute that the University of California is both a contractor and a nonprofit organization, within the meaning of sections 201(c) and (i) of the Act, and that the Buckberg Solution is a subject invention that was reduced to practice during the performance of work under a funding agreement with a federal agency. The Act therefore applies. The analysis moves to the questions of whether the Act was violated, and if so, what the consequence of the violation must be.

Section 202(c)(1) requires a contractor to disclose within a reasonable time any subject invention to the federal agency that issued the funding agreement. See 35 U.S.C.A. § 202(c)(1). Federal regulations define a reasonable time as within two months of the date the invention was created. See 48 C.F.R. § (c)(1). After the invention is disclosed to the federal agency, the Act requires the contractor to "make a written election within two years after disclosure to the federal agency ... whether the contractor will retain title to a subject invention." 35 U.S.C.A. § 202(c)(2). If the contractor elects to retain title, section 202(c)(5) provides that "the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practice for or on behalf of the United States any subject invention throughout the world." Federal regulations further require a contractor to "agree to execute or to have executed and promptly deliver to the Federal Agency all instruments necessary to (I) establish or confirm the rights the government has throughout the world in those subject inventions to which the Contractor elects to retain title...." 48 C.F.R. § 52.277(f)(1)(I). The regulations further require the contractor to "include ... within a patent issuing thereon

covering the subject invention, the following statement, 'The invention was made with Government support under (identify the contract) awarded by (identify the Federal agency). The Government has certain rights in the invention.'" Id. § 52.277(f)(4).

There is no dispute here that the University of California complied with each of these requirements. The University timely disclosed the Buckberg Solution to the NIH. On December 13, 1985, it executed a confirmation of the NIH's paid-up, irrevocable license to the invention. (See Def. Ex. E.) The '515 patent contains the statement required by regulation section 52.277(f)(4).

However, in 1987, the University of California decided to forgo its rights to the Buckberg Solution. At that point, Dr. Buckberg requested, pursuant to section 202(d) of the Bayh-Dole Act, to obtain the NIH's permission to seek patent rights in his own name. Section 202(d) provides: "If the contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder." 35 U.S.C.A. § 202(d). Among the regulations promulgated under the Act is 37 C.F.R. § 401.9, which provides that "[a]gencies which allow employee/inventor of the contractor to retain rights to a subject invention made under a funding agreement with a small business or nonprofit organization, as authorized by 35 U.S.C.A. § 202(d), will impose upon the inventor at least those conditions that would apply to a small business contractor under paragraphs (d)(1) and (3); (f)(4); (h); and (j) of the clause at § 401.14(a)." 37 C.F.R. § 401.9.

On September 23, 1987, the NIH assented to Dr. Buckberg's request to retain title to what would become the Buckberg Solution. However, the NIH's assent stated that "the inventor shall grant to the Government of the United States a nonexclusive, irrevocable, royalty-free license to the

invention for government purposes." The defendants have submitted to the court Dr. Buckberg's admission that he did not execute a such license. Although Rule 37(b) permits a party to move to withdraw or amend an admission, the plaintiffs failed to file such a motion prior to the close of discovery. Consequently, even though Dr. Buckberg has provided, in opposition to this instant motion, a declaration that he did execute a license to the government, under Federal Rule 37(b), the court is obligated to treat Dr. Buckberg's admission as "conclusively establish[ing]" that he did not execute any such license.

The defendants, therefore, have shown that Dr. Buckberg has failed to comply with the Bayh-Dole Act. The question, therefore, moves to what the Act prescribes as consequence of Dr. Buckberg's noncompliance.

The defendants argue that Dr. Buckberg's noncompliance entails that Dr. Buckberg never obtained title to the '515 patent. The problem with the defendants' argument, however, is that this consequence is nowhere mentioned in the Act. Rather, the only consequence mentioned in the Act for failing to comply with its requirements is that the federal government will retain the right to receive title to the invention. For instance, if a contractor entirely fails to disclose the existence of an invention to the relevant federal agency, the Act provides that "the Federal Government may receive title to any subject invention not disclosed to it within such time." 35 U.S.C.A. § 202(c)(1) (emphasis added). Similarly, if a party fails to make a timely written election of its intent to retain title to the subject invention, the Act provides that "the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect within such time." 35 U.S.C.A. § 202(c)(2) (emphasis added). The Federal Circuit has confirmed that the phrase "the Federal Government may receive title" means that the federal government has discretion to determine whether to take title to the invention.

See Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee, 389 F.3d 1243, 1250 (Fed.Cir.2004) ("We agree with the [Armed Services] Board [of Contract Appeals] that FAR 52.227.11(d) vests discretion in the government in determining whether to invoke forfeiture when an invention has not been correctly disclosed to it.").

In support of their argument that the Act divests Buckberg of title, the defendants rely on TM Patents, L.P. v. IBM Corp., 121 F.Supp.2d. 349, 368- 69 (S.D.N.Y.2000). However, the court will not follow TM Patents because it is at odds with Campbell Plastics. Whereas Campbell Plastics states that a violation of the Bayh-Dole Act gives the Federal Government discretion to take title to a subject invention, see 389 F.3d at 1250 TM Patents states that the forfeiture is automatic. See 121 F.Supp.2d. at 368-69 ("Failure to comply with the conditions of § 202 results in the Government acquiring title."). On this question of patent law, this court is obligated to follow the Federal Circuit's authority as against the Southern District of New York.[6]

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[6] Furthermore, the *TM Patents* decision is not persuasive because its legal conclusions are not supported by the authorities upon which the decision relies. In support of the proposition that the Bayh-Dole Act operates an automatic forfeiture on the patent rights of parties who do not fully comply with the Act, the *TM Patents* court relies on the following quotation from *Thermalon Industry, Ltd. v. United States,* 34 Fed. Cl. 411, 414 (Fed.Cl.1995): "NSF [a government entity] acquires title to a patent, rather than a license, *inter alia,* in the event the grantee fails to disclose within a reasonable time that the patented invention resulted from the grant." Although the *TM Patents* court relies on this quotation as an authoritative interpretation of the Bayh-Dole Act, the quotation is no such thing. Instead, the quotation is part of a recitation of the provisions of a contract between the National Science Foundation (NSF) and Thermalon Industries. The *Thermalon* court was not even attempting to construe the Bayh-Dole Act, much less give an authoritative interpretation of it. Indeed, the *Thermalon* case was a breach of contract action for damages having nothing to do with patent rights. Thus, the *TM Patents* opinion is contrary to the language of the Act, contrary to the binding authority of the Federal Circuit, and unsupported by the authority to which it cites.

Based on the language of the statute and its interpretation by the Federal Circuit, the court determines that Dr. Buckberg's failure to comply with the Bayh-Dole Act leaves the patent subject to the Federal Government's discretionary right to take title to the '515 patent. In addition to the fact that this outcome is supported by the statutory language and applicable case law, the court finds that this conclusion furthers the purpose of the Bayh-Dole Act by interpreting the law to preserve the government's rights to inventions created through government funding and also by declining to interpret the law to provide additional defenses to alleged patent infringers.

Because the defendants have failed to present any evidence that the NIH has taken title to the '515 patent, the court finds that the defendants are not entitled to judgment on the ground that Dr. Buckberg is not the owner of the patent. Accordingly, the defendants' motion for judgment on the pleadings for lack of ownership of the '515 patent is due to be DENIED.

II.

The Validity of the '515 patent

The plaintiffs move for summary judgment as to the defendants' counterclaim and affirmative defenses that the '515 patent is invalid.

A. Summary Judgment Standard

Under Federal Rule of Civil Procedure 56(c), summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986); Chapman v. AI Transport, 229 F.3d 1012, 1023 (11th Cir.2000). The party asking for summary judgment always bears the initial responsibility of informing the court of the basis for its motion and identifying those portions of the

pleadings or filings which it believes demonstrate the absence of a genuine issue of material fact. Celotex Corp., 477 U.S. at 323. Once the moving party has met his burden, Rule 56(e) requires the nonmoving party to go beyond the pleadings and by his own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial. Id. at 324.

All reasonable doubts about the facts and all justifiable inferences are resolved in favor of the non-movant. Chapman, 229 F.3d at 1023; Fitzpatrick v. City of Atlanta, 2 F.3d 1112, 1115 (11th Cir.1993). A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); Chapman, 229 F.3d at 1023. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted. Anderson, 477 U.S. at 249.

On a motion for summary judgment, the burden of proof that applies is the "the evidentiary standard of proof that would pertain at a trial on the merits." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 962 (Fed.Cir.2001). Because patents are entitled at law to a presumption of validity, see 35 U.S.C.A. § 282, a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence of invalidity so that no reasonable jury could invalidate the patent. Id. Additionally, when a party attacks a patent based upon prior art that was considered by the PTO, "he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents." Am. Hoist &

Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed.Cir.1984).

B. Facts

As described above, the Buckberg Solution consists of an amino acid enriched cardioplegic solution having (1) a calcium ion concentration of between 50-300 umol; (2) a concentration of metabolizable substrate between about 400-1000 mg%; and (3) an osmolality of between about 400-500 mOsmol/kg. At these levels, the solution combines the characteristics of being hypocalcemic, hyperglycemic, and hyperosmotic, and it possesses these characteristics within the precise ranges claimed in the patent.

The prior art in the area of cardioplegia that form the basis of the defendants' claims of invalidity are as follows. In 1978, Dr. David Follette, et al., published in the journal Surgical Forum an article describing a cardioplegic solution that was hypocalcemic (.5 mEq/L calcium).[7] The solution described by Dr. Follette was not amino acid enhanced. In 1979, Dr. Buckberg published an article entitled "A Proposed 'Solution' to the Cardioplegic Controversy" in which he disclosed a solution that was hypocalcemic (500 umol calcium) and moderately hyperosmotic (>400 mOsmol/L).

In 1980, in what the parties refer to as the "Dyson Reference," Drs. Buckberg and Charles Dyson described their "standard cardioplegic solution" as being hyperosmotic (360 mOsmol/L) and hypocalcemic with a metabolizable substrate, in this case dextrose, of over 2000 mg%. The Dyson Reference was later updated and, in 1982, it was published as Chapter 22 of the Textbook on Clinical Cardioplegia (the "Chapter 22 Reference"). Neither the Dyson Reference nor the Chapter 22 Reference describe solutions that are amino acid enhanced.

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[7] The defendants' expert, Dr. Robert Riggs, reports that .5 mEq/L converts to 250 umol calcium.

In 1981, Dr. David Follette, et al., published an article where the authors described a cardioplegic solution that was hypocalcemic and hyperosmotic, but at various levels of calcium concentration and levels of osmolarity. The article endorses as "ideal" a calcium concentration of 500 umol and an osmotic pressure of 351 +/-5 mOsmol/L. However, the article did not disclose any amount of glucose or other metabolizable substrate in the solution, nor was it amino acid enriched.

In 1982, Dr. Phillip Menasche, et al., published an article wherein the authors disclosed a cardioplegic solution that was hypercalcemic (2500 umol calcium), moderately hyperosmotic (395 mOsmol/L), and hyperglycemic (10 gm/L glucose).[8] Menasche based his solution on a 1981 article by Dr. Follette, although Menasche's solution also was amino acid enriched and contained glucose. The Menasche article described a clinical trial testing a procedure called retrograde coronary sinus profusion as a means of delivering cardioplegia.

In 1983, Dr. Kito published an article describing a cardioplegic solution that was hyperglycemic with a glucose range of 2500-3500 mg%. In 1983, Dr. Rosenkrantz described a cardioplegic solution that was hypocalcemic (500 umol calcium) and moderately hyperosmotic (360 mOsmol/L) but that did not disclose any glucose concentration or recommend amino acid enrichment. In 1984, Dr. Hashimoto disclosed a cardioplegic solution containing 2000 mg% of glucose.[9]

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[8] The defendants' expert, Dr. Riggs, states that 10 gm/L of glucose would produce a glucose concentration of approximately 1000 mg%. (*See* Riggs Decl. (doc. 239, Defs.Ex. 2) ¶ 11.)

[9] Dr. Riggs, the defendants' expert, lists additional references as relevant prior art, but there is no dispute that the remaining references, including the Menasche 1984, the Irasawa 1983, and the Bercot 1979 References disclose cardioplegic solutions that differ in material respects from the Buckberg Solution. Reflecting this, in their brief opposing

The application that led to the '515 patent was filed on August 21, 1985. On November 20, 2003, the defendants filed a Request for Ex Parte Reexamination of the '515 patent with the PTO. All of the references cited in the Information Disclosure Statements submitted during the reexamination proceedings were considered by the Examiner. On February 10, 2005, a Notice of Intent to Issue Ex Parte Reexamination Certificate was issued by the Examiner. The Examiner stated that "[n]one of the references, either taken individually or taken as a whole, suggest the cardioplegia solution within the limitations claimed." (See Notice of Intent to Issue Reexamination Cert., Pla. Ex. JJ.)

C. Analysis

The defendants assert a counterclaim for a declaration that the '515 patent is invalid and raise invalidity as an affirmative defense. The defendants' claims of invalidity are based upon anticipation under section 102 of the patent law, the public use bar under section 102 of the patent law, indefiniteness under section 115 of the patent law, and obviousness under section 103 of the patent law.

1. Anticipation Under § 102

"Anticipation under 35 U.S.C.A. § 102 means lack of novelty, and is a question of fact." Beckson Marine, Inc. v. NFM, Inc., 292 F.3d 718, 725 (Fed.Cir.2002). To prevail on their claim that the '515 patent is void because it was anticipated, the defendants must show, by clear and convincing evidence, "that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed.Cir.2000).

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summary judgment, the defendants make no arguments based upon these additional references.

The defendants predicate their claim of lack of novelty on an article authored by Phillip Menasche, et al., published in 1982 in the Society of Thoracic Surgeons journal. However, this reference plainly fails to support the defendants' claim of anticipation on two grounds.[10] First, the solution described in the Menasche 1982 Reference discloses a calcium concentration of 2500 umol, which far exceeds the Buckberg Solution's claimed range of 50-300 umol. In fact, the Menasche solution is significantly hyper calcemic rather than hypo calcemic. Although the defendants argue that a person skilled in the art could add sufficient chelating agent to reduce the calcium concentration to the ranges claimed in the '515 patent, there is nothing in the text of the article to motivate a reader to do so. To the contrary, because the article recommends formulating a solution that is strongly hypercalcemic to begin with, it would be contradictory to view the article as disclosing or teaching or in any way encouraging the formulating of a strongly hypocalcemic solution.

Accordingly, the defendants have failed to provide clear and convincing evidence creating an issue of fact as to whether the '515 patent is invalid for having been anticipated. The plaintiffs are entitled to summary judgment on this ground.

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[10] The plaintiffs object to the defendants' reliance on this reference because it was not disclosed until three years after the close of the original discovery deadline. Ordinarily, this argument would prevail and the untimely disclosed evidence would be disregarded. *See Sosa v. Airprint Sys., Inc.*, 133 F.3d 1417, 1418 (11th Cir.1998). However, because the court reopened discovery in this action and permitted the parties to file new motions for summary judgment based upon evidence produced in the most recent round of discovery, the court can see no principled ground for viewing this evidence as untimely, nor can the court perceive that the plaintiffs will suffer any prejudice by the court's consideration of the reference given their opportunity to conduct additional discovery on the reference.

2. Public Use Under § 102

Section 102 of the patent law provides that a person "shall be entitled to a patent unless ... (b) the invention was ... in public use or on sale in this country, more than one year prior to the date of the application in the United States." 35 U.S.C.A. § 102(b). As with any other challenge to the validity of a patent, the burden of proof to prove public use of the patented invention more than a year prior to the filing of the patent application is on the party attacking the patent. See TP Labs. v. Professional Positioners, Inc., 724 F.2d 965, 971 (Fed.Cir.1984). Furthermore, it is well-established that "if a use is experimental, though not secret, 'public use' is negated." Id.

The defendants base their claim of public use on an article that Dr. Buckberg published in 1986 in The Journal of Thoracic and Cardiovascular Surgery. The article reports that, from May 1984 to April 1985, patients were clinically treated at UCLA and Long Beach Memorial Hospital for acute coronary occlusion with a cardioplegic solution within the ranges within the '515 patent. Although Dr. Buckberg testified that he did not remember whether he began treating the patients with the cardioplegic solution before or after August 21, 1984, the defendants ask the court to infer, on the basis of the article, that some use of the cardioplegia occurred prior to this date.

The defendants' reliance on the 1986 article falls short of clear and convincing evidence from which a jury could find that the '515 patent is invalid due to public use. It is well-established that experimental use of an invention does not constitute public use under section 102(b). The fact that Dr. Buckberg published his findings in a scientific journal strongly supports the conclusion that the use was experimental. This conclusion is further supported by the fact that Dr. Buckberg relied on the data obtained from the clinical trials to support his application for a patent on the Buckberg Solution. (See '515 patent, at 2.) The defendants

offer no evidence contradicting the plain appearance that Dr. Buckberg's clinical use of the invention was experimental.

Accordingly, the plaintiffs are entitled to summary judgment on the defendants' claims that the '515 patent is invalid due to public use under section 102 of the patent law.[11]

3. Obviousness Under § 103

Section 103 of the patent law requires provides that "[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C.A. § 103(a). Obviousness is an issue of law based upon four factual inquiries, to wit: "(a) the scope and content of the prior art; (b) the differences between the prior art and the claims at issue; (c) the level of ordinary skill in the art; (d) the objective evidence of nonobviousness." Custom Accessories, Inc. v. Jeffrey-Allen Indus., Inc., 807 F.2d 955, 958 (Fed.Cir.1986). Furthermore, "when determining the patentability of a claimed invention which combines two known elements, the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1371 (Fed.Cir.2000). However, one must not "use hindsight reconstruction to pick and choose among isolated disclosures

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[11] The plaintiffs submitted, along with their reply brief, a declaration from Dr. Buckberg indicating that the clinical treatment was secret, and therefore not public. However, the court struck that declaration, along with several other pieces of evidence, because they were untimely submitted under the Northern District of Alabama's Uniform Guidelines Regarding Summary Judgment. (*See* Order, dated July 26, 2005, doc. 266.)

in the prior art to deprecate the claimed invention." Id. "[T]he court requires the challenger to show a motivation to combine the references that creates the case of obviousness." Beckson Marine, Inc. v. NFM, Inc., 292 F.3d 718, 727-28 (Fed.Cir.2002) (brackets omitted).

The defendants base their claim of obviousness on the opinion of Dr. Riggs, on the twelve references cited in his expert reports, on the Dyson/Chapter 22 Reference, and on the Menasche 1982 Reference. With the exception of the Menasche 1982 Reference that the court discussed above, there appears to be no dispute that no single Reference embodies all of the '515 patent's claims.[12] Consequently, the defendants rely on an argument that the prior art reveals a motivation to combine the elements present in the prior art in a way that obviously would lead to the formulation of the Buckberg Solution.

The defendants make this argument with a series of legal obstacles arrayed against them. In addition to the patent possessing a statutory presumption of validity, the finding of the PTO Examiner as expressed in the Reexamination Certificate itself is evidence of the invention's lack of obviousness, and the court is obligated to afford the Examiner's conclusion some deference. See Am. Hoist & Derrick Co., 725 F.2d at 1359. Furthermore, the plaintiffs have adduced substantial objective evidence of the invention's nonobviousness. Regarding the invention's commercial success, the defendants not only admit that its success is substantial, but they acknowledge that virtually no substitute products exist: "CAPS has an extremely strong position in the outsourcing of cardioplegia and faces competition from only one or two major companies and a

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[12] *See* Holman Decl. (Pla.Ex. VV) ¶¶ 38-64. Furthermore, as the court ruled above, the Menasche 1982 Reference has a calcium concentration that plainly exceeds the range claimed in the '515 patent, and the defendants have produced no clear and convincing evidence that it contains a glucose concentration within the claimed ranges.

handful of regional providers such as ACS. CAPS has no competitors in the outsourcing of amino acid enriched cardioplegia except ACS, but for ACS, no other substitute product exists." (Defs. Opp. to Pla.3d Mot. for Summ. J at ¶ (B)(1)).

Moreover, Charles Wall admitted that he copied Dr. Buckberg's solution to formulate ACS' cardioplegia products. (Wall Dep. at 29-30, 48.) Additionally, several prominent cardiovascular surgeons have filed declarations supporting the nonobviousness of the Buckberg Solution in the prior art. Included among these surgeons is Dr. Follette, who authored many of the references relied upon by the defendants to support their claim of obviousness. (See Def. Ex. X.)

Thus, to prevail against this evidence, defendants require extremely powerful evidence of a motivation to combine to establish that the Buckberg Solution was obvious in light of the prior art. Such evidence simply is lacking. [13] Although it is possible to cherry-pick from the prior art the elements that Dr. Buckberg synthesized in the Buckberg Solution, each reference cited by the defendants teaches

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[13] Although the defendants submit the opinion of Dr. Riggs that one can derive a motivation to combine from the prior art, Dr. Riggs's opinion does not prevent the granting of summary judgment because obviousness is a question of law, not one of fact. *See Custom Accessories, Inc.*, 807 F.2d at 958. Thus, Dr. Riggs's opinion, to the extent that it attempts to establish that the Buckberg Solution was obvious in light of the prior art, amounts to an opinion on an ultimate question of law. Furthermore, Dr. Riggs's opinion is flawed because it attempts to demonstrate a motivation to combine by focusing only on Dr. Buckberg's prior publications, and using the development in Dr. Buckberg's writing to predict what Dr. Buckberg's ideal solution would have been in 1985. This approach is flawed because Dr. Riggs's motivation for focusing exclusively on Dr. Buckberg's writing is his hindsight knowledge that Dr. Buckberg ultimately would synthesize the cardioplegia patented by the '515 patent. The law is clear that using hindsight to retrace the creation of an invention is an improper form of analysis to support a claim of obviousness. *See Beckson Marine, Inc.*, 292 F.3d at 727-28.

away from the invention to the same degree that it teach towards it.

The reason for this is that the prior art leading up the Buckberg Solution reveals no discernable trend in the levels disclosed in cardioplegia. For instance, the Menasche 1982, the Menasche 1984, and the Bercot 1979 References all teach hypercalcemia (1250-2500 umol calcium) in cardioplegia. However, other references published during the same period-such as Follette 1978, Follette 1981, the Rosenkrantz 1983, and the Dyson/Chapter 22 References-counsel the opposite, i.e., hypocalcemia. Many references during this period contain no teaching on glucose, see, e.g., Menasche 1984, Irisawa 1983, Follette 1981, Rosenkrantz 1983, Buckberg 1979, and Bercot 1979. Those that do contain teachings on glucose--e.g., Kito 1983, Hashimoto 1984, Follette 1977, and Dyson/Chapter 22-teach hyperglycemia at ranges far in excess of the ranges claimed in the '515 patent.

Reading the prior art references proffered by the defendants, the writing was not on the wall. One could only produce the Buckberg Solution if one had the special insight to know precisely which lines of the prior art to reject and which to accept.[14] As attested to by the nineteen surgeons who provided declarations to support the nonobviousness of Dr. Buckberg's invention during the application for a patent,

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[14] As discussed above, the Menasche 1982 cardioplegic solution is the one disclosed in the prior art that is most similar to the Buckberg Solution. However, the Menasche 1982 Reference addresses a separate topic. The article lists the formula of the cardioplegic solution only once in a table and it discloses the constituent elements of cardioplegia only briefly and incompletely in the text. The article makes no references of any particular benefits arising from the particular formulation used and it makes no attempt to encourage readers to use a similar solution. The article provides no guidance whatever as to which of the cardioplegia's elements should be pursued and which should be rejected. Consequently, the article fails to provide any motivation to reject its teaching on hypercalcemia, while accepting its teaching as to moderate hyperosmolality and hyperglycemia.

Dr. Buckberg alone possessed the rare insight necessary to separate the fruitful lines of development from the futile. There is no clear and convincing evidence to the contrary.

Given the mass of objective evidence as to nonobviousness, and in light of the substantial legal presumptions in favor of validity, and the failure of the defendants to demonstrate any expressly stated or inherent motivation to combine the prior art to produce the invention, the plaintiffs are entitled as a matter of law to a judgment that the '515 patent is not invalid for obviousness. Accordingly, the plaintiffs are entitled to summary judgment as to the defendants' claim that the patent is void for obviousness under section 103.

D. Indefiniteness

The defendants argue that the '515 patent is void for indefiniteness. A patent is unenforceably indefinite when one skilled in the art would not understand the bounds of the claim when read in light of the specification. See Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385 (Fed.Cir.1986). If the "claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." Id. An assertion of indefiniteness must be proved by clear and convincing evidence. See Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941 (Fed.Cir.1990). Close questions of indefiniteness are "properly resolved in favor of the patentee." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1380 (Fed.Cir.2001).

The defendants argue that the '515 patent is indefinite for two reasons. First, they argue that the phrase "adapted to be diluted" is indefinite. Second, they argue that the word "maintaining," as used in the patent's claims, is indefinite.

The defendants' indefiniteness challenges fail, however, because they lack any evidentiary support. Critically, all the experts who have offered their opinions in

this action have been able to construe the claims of the '515 patent. Furthermore, the defendant, Charles Wall, attests that he understood the claims of the '515 patent well enough to design ACS' products to avoid infringement. Thus, all the evidence supports the conclusion that the claims of the '515 patent are not unenforceably indefinite, and there is no probative evidence to the contrary.

Accordingly, the plaintiffs are entitled to summary judgment on the defendants' affirmative defense and counterclaim that the patent is unenforceably indefinite.

E. Conclusion

The plaintiffs' motion for summary judgment as to the defendants' affirmative defense and counterclaim that the '515 patent is invalid is due to be GRANTED.

III.

Inequitable Conduct

Both parties move for summary judgment on the defendants' claim of inequitable conduct in the procurement of the '515 patent.

A. Sufficiency of Defendants' Pleadings

Federal Rule of Civil Procedure 9(b) states that claims alleging fraud must be pled with particularity. Fed.R.Civ.P. 9(b). Inequitable conduct, while a broader concept than fraud, must also be pled with particularity. Ferguson Beauregard/Logic Controls v. Mega Sys., 350 F.3d 1327, 1344 (Fed.Cir.2003). Rule 9(b) states that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." Fed.R.Civ.P. 9(b).

"Inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with intent to deceive." Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368,

1373 (Fed.Cir.2000) (quotation and citation omitted). To satisfy the particularity requirement of Rule 9(b), ACS must plead "(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the statement; (3) the content and manner in which these statements misled the Plaintiffs; and (4) what the defendants gained by the alleged fraud." Brooks v. Blue Cross & Blue Shield of Fla., Inc., 116 F.3d 1364, 1380-81 (11th Cir.1997).[15] Mere conclusory allegations of fraud are insufficient. Id. Allegations of inequitable conduct must give CAPS notice of the particular misconduct alleged so that it can defend against the charge. ACS must offer specific facts that CAPS can either deny or controvert. See Weatherford Int'l, Inc. v. Casetech Int'l, Inc., No. Civ.A.H.-0305383, 2005 WL 1745457, at *1 (S.D.Tex. July 25, 2005). In holding that inequitable conduct must comply with Rule 9(b), the Federal Circuit has ruled that it would not "infer facts to support a claim that must be pled with particularity." Ferguson Beauregard/Logic Controls, 350 F.3d at 1344.

In their Third Amended Answer and Counterclaim, the defendants asserted the following allegations in relation to inequitable conduct:

> Affirmative Defenses
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> ...
>
> 11. Each claim of the '515 patent is void and unenforceable by virtue of the failure of patentee to advise the Patent Office of prior art which was material to the examination of the application.
>
> ...
>
> Counterclaims
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> ...

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[15] The Federal Circuit applies the law of the regional circuit where the case arises as to procedural issues not unique to patent law, such as those under Rule 9(b). *See Ferguson Beauregard/Logic Controls*, 350 F.3d at 1344.

> 9. Upon information and belief, during prosecution of the '515 patent, the patentee failed to disclose all of the relevant prior art known to it, and thereby failed to satisfy its duty of disclosure to the United States Patent and Trademark Office. Additionally, by manipulation of various measurements and units, the patentee sought to mislead the Patent and Trademark Office regarding the relationship between the claimed invention and the prior art. The '515 patent is unenforceable as a result of this failure to disclose and/or inequitable conduct during the prosecution of the patent.
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> ...
>
> 19. The '515 patent is invalid and unenforceable.

Third Amended Answer and Counterclaim, Affirmative Defenses, ¶ 11; Counterclaims, ¶¶ 9, 19.

These allegations fail to state a defense or claim of inequitable conduct with particularity. The allegations do not provide the specific details required by Rule 9(b), such as the precise statements, documents, or misrepresentations made; the time, place, and person responsible for the statement; or the content and manner in which these statements misled the PTO. See Brooks, 116 F.3d at 1380-81. The allegations fail to provide CAPS with specific facts to deny or controvert. Instead, the allegations merely restate the elements of an inequitable conduct defense. They are prototypical conclusory allegations.

Accordingly, the defendants have failed to plead an inequitable conduct defense with particularity as required by the Federal Circuit's case law.[16] The plaintiffs are therefore

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[16] The defendants rely upon *Great American Indemnity Co. v. Brown*, 307 F.2d 307, 308 (5th Cir.1962), for the proposition that objections under Rule 9(b) are waived if the objections are not presented via a Rule 12 motion. *Great American Indemnity Co.* is distinguishable, however, because it addresses the issue of pleading special damages and arises on an appeal after the entry of judgment. The case does not, and cannot, stand for the proposition that a party waives its 9(b) arguments if

entitled to judgment as a matter of law on the defendants' counterclaims and defenses of inequitable conduct.

B. Alternative Ruling on the Merits

Even if the defendants had adequately pled their claims of inequitable conduct, the court nevertheless would grant the plaintiffs' motion for summary judgment on the claims on their merits.

"Inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with intent to deceive." Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1373 (Fed.Cir.2000). ACS's unpled claims of inequitable conduct include an assertion that CAPS failed to disclose to the PTO the Dyson/Chapter 22 Reference, and that CAPS misrepresented the data contained in Figure 4 of the patent.

ACS's claim based upon the Dyson/Chapter 22 Reference fails because ACS has adduced no evidence, much less clear and convincing evidence, showing that the Dyson/Chapter 22 Reference was material or that it was omitted with the intent to deceive. First, the Dyson/Chapter 22 Reference discloses no prior art that was not already before the Examiner. Although the Dyson/Chapter 22 Reference discloses a calcium concentration of 150 umol that is within the range claimed by the '515 patent, the

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it moves for judgment on an inadequately pled defense for the first time at the summary judgment stage. Furthermore, the court stands by its prior rulings that the defendants failed to show good cause for amending its pleadings to make additional allegations of inequitable conduct after the deadline for amending pleadings had passed. Lastly, the defendants are mistaken to rely on the court's Order, dated May 5, 2005 (doc. 214), as ruling that the defendants adequately pled a defense of inequitable conduct. That Order merely ruled that defendants' discovery was relevant under Rule 26(b)(1) to allegations made in the defendants' Third Amended Answer and Counterclaim. The Order did not, however, review, analyze, or in any way rule upon the sufficiency of the defendants' allegations of inequitable conduct under Rule 9(b).

Follette 1978 Reference does so as well. Furthermore, the Dyson/Chapter 22 Reference teaches a glucose concentration (approximately 2160 mg%) that far exceeds the concentration of the '515 patent, although it mirrors glucose concentrations disclosed in the prior art references that were before the patent examiner, such as the Kito 1983, Hashimoto 1984, and Follette 1977 References. Thus, the Dyson/Chapter 22 Reference is merely cumulative and not material. See Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1574-75 (Fed.Cir.1997) (no inequitable conduct where the uncited reference teaches no more than what a reasonable Examiner would consider to be taught by the prior art already before the PTO).

Second, ACS presents no evidence that Dr. Buckberg intentionally withheld the references to deceive the Examiner as to the state of the prior art. The only evidence of Dr. Buckberg's intent indicates that the materials were omitted for innocent reasons, i.e., because the subject of the Dyson/Chapter 22 Reference was not the formula of the cardioplegia, but rather was the delivery system used to administer the cardioplegia. (See Buckberg Decl., Pla. Ex. WW, 22; Holman Decl., Pla. Ex. VV, ¶ 56.)

Because there is no evidence of either materiality or intent to deceive, the plaintiffs are entitled to judgment as to the defendants' unpled defense and counterclaim of inequitable conduct based upon the Dyson/Chapter 22 Reference.

The defendants' second basis for their inequitable conduct claim is Figure 4 of the '515 patent. The defendants allege that Figure 4 purports to record the results of the use of a cardioplegic solution with an osmolarity of 400- 500, when in reality the solution had a osmolarity of 360-380 mOsmol. [17] This claim fails, however, because the

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[17] Defendants base their argument of misrepresentation on the assertions (1) that the research leading to the '515 patent is the same as the research reported in Article IX of the Journal of Thoracic and

defendants present no evidence, other than attorney speculation, that Figure 4 misstates anything, nor have defendants produced any evidence to indicate that, if a misstatement was present, it was made intentionally. To the contrary, it is undisputed that the article upon which the defendants rely to show that Figure 4 is incorrect was submitted to the Examiner. (See Def. Ex. P.) This is strong evidence that Dr. Buckberg did not intend to deceive the Examiner and the defendants have failed to rebut it. Accordingly, the plaintiffs are entitled to summary judgment as to the defendants' counterclaim and defense of inequitable conduct based upon the alleged misrepresentation contained in Figure 4.

C. Conclusion

The plaintiffs' motion for summary judgment as to the defendants' counterclaim and affirmative defense of inequitable conduct is due to be GRANTED.

IV.

Validity of the Certificate of Correction

Along with their motion on inequitable conduct, the defendants argue that the certificate of correction is invalid. The defendants base their argument on Superior Fireplace Co. v. Majestic Prods. Co., 270 F.3d 1358, 1375 (Fed.Cir.2001), which holds that a certificate of correction that corrects "mistakes of minor character" may not correct a mistake that broadens a patent's claims. Because the court already has held that the certificate of correction issued on the '515 patent corrected "a mistake of minor character," (Order, dated May 2, 2002, doc. 64, at 1), the defendants

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Cardiovascular Surgery, and (2) that Article IX reports the data differently from how the data is reported in the '515 patent. (*See* Def. Ex. Z (Bradley S. Allen, M.D., *et al., Studies of Controlled Reperfusion After Ischemia: IX. Reperfusate Composition: Benefits of Marked Hypocalcemia and diltiazem on Regional Recovery*, J. OF THORAC. CARDIOVASC SURG. v. 92, at 564-572 (1986))). Apparently making them for the first time in their summary judgment briefs, defendants fail to present any evidence to support either assertion.

argue that the certificate is invalid because the certificate accomplished a broadening of the scope of the patent. Furthermore, the defendants submit additional evidence that they argue demonstrates that the COC expanded the claims of the '515 patent. However, the court already has ruled that "the defendants may present the question of the COC's validity to the jury." (Id.)

To the extent that the defendants' argument constitutes a request for the court to revisit this ruling, the court declines the request. The defendants' evidence tends to show that osmolarity and osmolality are not identical measures. (See, e.g., Riggs Decl. (doc. 239, Defs.Ex. 2).) However, there continues to be a question of fact as to whether "an increased level of between about 400-500 mOsmol/kg" is broader than "an increased level of between about 400-500 mOsmol/L." Accordingly, the defendants' motion for summary judgment on the validity of the certificate of correction is due to be DENIED.

V.

Infringement

The defendants move for summary judgment on the plaintiffs' claims of infringement prior to the issuance of the certificate of correction ("COC"). The plaintiffs move for summary judgment on the claims of infringement after the issuance of the COC. Each motion is addressed in turn.

A. Legal Standard

Evaluating claims of infringement involves two steps, "(1) claim construction to determine the scope and meaning of the claims asserted to be infringed, followed by (2) a determination of whether the properly construed claim encompasses the accused [device or] method." See Robotic Vision Sys., Inc. v. View Eng'g, Inc., 189 F.3d 1370, 1373 (Fed.Cir.1999). Because the plaintiffs' claims of infringement are before the court on summary judgment, the summary judgment standard laid out above applies.

B. Claim Construction

The '515 patent has three independent claims: claims 1, 7, and 13. Each independent claim describes treatment for the human heart for the purpose of preventing and reversing muscle damage due to ischemia. Claim 1 describes the patented treatment as "an amino acid enriched cardioplegic solution for use in treating human hearts"; whereas claim 7 describes the treatment more generically as "a method for treating human hearts"; while claim 13 describes the treatment as "[a] composition of matter for introduction into human hearts". All three independent claims require: (1) a calcium concentration of "between about 50-300 umol," (2) a metabolizable substrate concentration of "between about 400-1000 mg%," and (3) an osmolality or osmolarity of "between about 400-500 mOsmol." '515 patent at 8-10.

Following the Markman hearing, the court issued orders on May 2, 2002, and again on September 4, 2003, construing the scope and meaning of the claim contained in the '515 patent. In the September 2003 Order, the court determined that the word "about" was to be given "its common sense meaning as a term of approximation, including numbers both below and above the ranges specified in the '515 patent." Markman Order, dated Sept. 4, 2003. The court further ruled that the limitation "between about 400-500" encompasses "a range of osmolarity or osmolality from 385-515." Id[18]

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[18] Although the court issued its construction of the patent's claims in its Orders of May 2, 2002, and September 4, 2003, the defendants now urge the court to amend its construction by construing the term "maintaining" as used in the '515 patent's claims 7 through 12. The defendants assert that the court should construe the term "maintaining" to mean that the '515 patent is not infringed unless a solution is within the claimed ranges throughout the treatment being administered to a patient. The defendants make this argument too late as the court already has issued its claim construction of the '515 patent. In the interest of finality, the issue of construction shall not be revisited or endlessly litigated. In addition, even if the asserted construction of the term "maintaining" were considered, the court would reject it. It is undisputed that it is impossible

1. Application of the COC

The defendants move for summary judgment on the plaintiffs' claims of infringement of the patent prior to the issuance of COC. The defendants make this motion in the alternative. Their primary position is that the COC does not apply to this suit because the suit was filed prior to the issuance of the COC. The defendants advance the instant motion for summary judgment only if the court rejects that argument and rules that the COC applies to this action as well as to all causes of action that accrued after the issuance of the COC. Accordingly, it would be premature for the court to rule on the defendants' instant motion without first determining the threshold question of whether the COC applies to this suit at all. Because the issue has been fully briefed by the parties, and because the resolution of this issue is necessary to determine the infringement questions pending before the court, the court will address whether the COC applies to this action.

The parties agree that the Federal Circuit's opinion in Southwest Software, Inc. v. Harlequin Inc., 226 F.3d 1280 (Fed.Cir.2000), provides the definitive authority as to the application of the COC. However, the parties quarrel over the meaning and effect of the Federal Circuit's holding in that case. At issue is whether the Federal Circuit held that a COC applies only to causes of action arising after the issuance of the COC or whether the COC applies only to lawsuits filed after the COC's issuance. The confusion as to how to interpret the Federal Circuit's opinion arises from the fact that the Southwest opinion uses the terms "lawsuit" and "cause of action" interchangeably throughout the opinion. Thus, the defendants quote the passages in Southwest

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to measure the levels of cardioplegic solutions after they have been administered to the patient. Thus, adopting the defendants' proposed construction would render the '515 patent uninfringeable due to the impossibility of measuring infringement. There is no merit to a claim construction that yields such an absurd result.

Software containing the phrase "lawsuit," see, e.g., id. at 1294 ("We hold that the certificate of correction that added the Program Printout Appendix is not to be given effect in this pre-certificate lawsuit."), while CAPS cites to the sentences where the phrase "cause of action" is used. See, e.g., id. at 1294 ("The certificate of correction is only effective for causes of action arising after it was issued.").

The plaintiffs observe that the reason the Federal Circuit could use the terms "cause of action" and "lawsuit" interchangeably in Southwest Software is that, under the particular facts of that case, the terms had the same effect. The defendant in Southwest Software ceased its allegedly infringing activity upon the filing of the lawsuit. See id. at 1287. Because the relevant certificate of correction in that case issued while the suit was pending, the plaintiff's lawsuit was filed, and all of the plaintiff's causes of action arose, prior to the COC's issuance. In contrast to the instant action, the Federal Circuit in Southwest Software did not confront a situation where some of the plaintiffs' causes of action arose prior to the issuance of the COC and some arose after its issuance. Because of these particular facts, Southwest Software must be interpreted with care.

Pursuant to such a careful reading, the court finds that the Southwest Software opinion supports the interpretation that a COC applies to causes of action arising after the COC's issuance, even if the lawsuit is filed prior to the COC's issuance. The Federal Circuit explained its holding as motivated, in part, by the court's desire to avoid the "illogical and unworkable result" that a patent holder might be able "to sue an alleged infringer for activities that occurred before the issuance of the certificate of correction" where the patent appeared invalid prior to the issuance of the COC but was rendered valid as a result of the COC. In such a case, the Federal Circuit opined that, prior to the issuance of the certificate, "reasonable competitors would be justified" in competing with the invention. See id. at 1295--1296.

This portion of the Federal Circuit's discussion is dispositive because the Federal Circuit's "illogical and unworkable result" would not be avoided if a COC applied to lawsuits filed after the issuance of a COC where the lawsuit sought to recover on causes of action accruing prior to the issuance of the COC. The only interpretation that avoids the result decried by the Federal Circuit is the interpretation that a COC applies only to causes of action arising after the issuance of the COC, regardless of when the lawsuit seeking to recover on those causes of action is filed.

Also supporting this interpretation of the Southwest Software opinion is the Federal Circuit's following caveat: "Finally, we point out that, for any cause of action arising after April 1, 1997, the date the certificate of correction issued, the certificate will be treated as part of the original patent. Therefore, any invalidity arising from the absence of the Program Printout Appendix only affects causes of action arising before the certificate issued. Put another way, if claim 1 is found to have been invalid without the Program Printout Appendix, the invalidity ceased on April 1, 1997, when the PTO issued the certificate of correction." Id. at 1297. This caveat simply is incompatible with the defendants' interpretation that a COC applies only to lawsuits filed after its issuance. Were the defendants' interpretation correct, the caveat would have no application since the lawsuit in Southwest Software obviously had commenced prior to the COC's issuance. The only interpretation that gives this dictum meaning is that the Federal Circuit was advising the district court that the plaintiff could proceed on any claims arising after the COC's issuance.

Honoring that instruction, this court will permit the plaintiffs here to do the same. For any causes of action for infringement of the '515 patent accruing after the issuance of the certificate of correction, the COC shall apply, provided, of course, that the certificate ultimately is held valid. For causes of action accruing prior to the issuance of the COC, the COC shall have no application.

C. Facts

In support of the claims of infringement, the plaintiffs present evidence from two experts. The first expert is Dr. Stanley B. Digerness. Dr. Digerness tested fourteen samples of the defendants' products that defendants provided during discovery. The defendants admit that they commercially produce solutions 1-12.

Dr. Digerness obtained blood samples from the cardiopulmonary bypass reservoir of five randomly selected patients. Dr. Holman provided an additional sample. After diluting each of the defendants' 14 sample crystalloid solutions with the collection blood samples, Dr. Digerness measured the calcium ion concentrations, metabolizable substrate concentration, osmolality, and pH of each sample.

Dr. Digerness found that, when mixed 1 to 4 with blood, all fourteen of the defendants' samples had calcium concentrations ranging from 90-199 umol; glucose concentrations ranging from 639-934 mg%; and amino acid concentrations ranging from 24.2 to 26.5 mmol/L, in an even proportion between glutamate and aspartate. Dr. Digerness also found that samples 1, 7, 9, 11, 12, 13, and 14 had a pH ranging from 7.353 to 7.603.

Dr. Digerness found that samples 1, 7, 9, 11, 12, 13, and 14 had osmolalities ranging from 368 to 442 mOsmol/kg, with twenty-two of the forty-six data points at 385 mOsmol/kg or greater. Sample 1 had osmolalities of 385, 391, and 398 when mixed with blood from patients 3, 1, and 2, respectively; and 394 when mixed with Dr. Holman's blood sample. Sample 7 had an osmolality of 385 and 393 when mixed with blood from patients 3 and 2, respectively. Sample 9 had an osmolality of 389 and 390 when mixed with blood from patients 2 and 4, respectively. Samples 11 and 12 had osmolalities of 392 when mixed with blood from patient 2. Sample 13 had an osmolality of 388 when mixed with blood from patient 2. Sample 14 had an osmolality of 386 when mixed with blood from patient 2. When mixed with the

blood of the other patients, however, these samples had osmolalities of less than 385. Furthermore, Dr. Digerness found that samples 2, 3, 4, 5, 6, 8, and 10 had osmolalities of less than 385 mOsmol/kg.

The plaintiffs' second expert is Dr. Hal Peterson. Dr. Peterson did not test solutions prepared by ACS. Instead, Dr. Peterson tested two solutions prepared by the plaintiff CAPS (CS-1 and CS-2) that Dr. Peterson attests is "chemically identical" to solutions sold by ACS to the University Hospital of New Orleans and Riverview Hospital. Dr. Peterson found that, when mixed with human blood in a 1:4 ratio, these samples, CS-1 and CS-2, had osmolalities ranging from 392 to 443 mOsmol/kg. Dr. Peterson attests that CS-1 and CS-2 are "chemically identical" to defendants' sample solutions 11 and 12.

The defendants present evidence from their expert, Dr. David R. Wade. Using the test results produced by Dr. Digerness, Dr. Wade calculated the osmolarity of the 14 cardioplegic solutions tested by the plaintiffs' experts. Dr. Wade calculated that each of the fourteen solutions had osmolarities of between 349 and 377 mOsmol/L.

D. Infringement Prior to the Issuance of the COC

Prior to the issuance of the COC on January 30, 2001, the '515 patent covered cardioplegic solutions with osmolarities of about 400-500 mOsmol/L. The court has interpreted the claim of between about 400-500 mOsmol/L to apply to all solutions having osmolarities within the range of 385-515 mOsmol/L. The testimony of Dr. Wade is undisputed that none of the defendants' 14 tested solutions came within the claims range of 385-515 mOsmol/L. Osmolarity is a necessary element of the '515 patent under all three of its independent claims. Consequently, there is no evidence of direct infringement of the patent as it read prior to the issuance of the COC.

The plaintiffs argue that questions of fact exist regarding whether the defendants nevertheless are liable for

infringement under the doctrine of equivalents. Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claims may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused patented invention." Warner Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 21, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997).

The defendants argue that plaintiffs are barred from invoking the doctrine of equivalents due to prosecution history estoppel. It is true that prosecution history estoppel, if applicable, would prevent the plaintiffs from taking advantage of the doctrine of equivalents.[19] However, there is no question that amendment-based prosecution history estoppel requires, at minimum, that the patentee have made a narrowing amendment to his or her claims during the patent review process. See Abbott Labs. v. Dey, L.P., 287 F.3d at 1103 ("[T]here can be no amendment-based estoppel with respect to this claim limitation [that was not amended during the prosecution of the patent]."). Rather, the only amendment that the defendants can point to is the addition of the language "at an increased level" in claims 1 through 6. Thus, the defendants can make no argument that the doctrine of equivalents does not apply to claims 7 through 17.[20]

In addition, the language that the defendants rely upon in no way limits the scope of claims 1 through 6. The defendants argue that the language "at an increased level" means that the doctrine of equivalents can only be applied to levels higher than the patent's claimed ranges of 400-500 mOsmol, but may not be applied to anything below that range. The court ascribes no such meaning to this phrase.

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[19] Prosecution history estoppel can be amendment-based or it can be argument-based. *See Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1103 (Fed.Cir.2002). Here, all of defendants' prosecution history estoppel arguments are amendment-based.

[20] The defendants, in their briefs, argue for amendment-based estoppel only. That is, they do *not* argue that argument-based prosecution history estoppel applies. *See,* doc. 235 at pp. 26-23.

Instead, the court interprets "at an increased level" to indicate merely that the cardioplegic solution must be hyperosmolar as compared to the normal osmolarities found in human blood. As human blood normally has an osmolarity of between 280 and 300 mOsmol, the '515 patent's requirement that the solution be hyperosmolar cannot be interpreted to limit the patent only to ranges above 400 mOsmol.

Indeed, the court rejected this very argument by the defendants during the claim construction phase of this action. At that time, the defendants argued that the language "at an increased level" required the court to limit the claimed range of between about 400 to 500 mOsmol as covering only ranges above, but nothing below, 400 mOsmol. The court rejected that argument and ruled that the patent's claim of "about 400-500 mOsmol" included "numbers both below and above the ranges specified in the '515 patent." (Markmen Order, dated Sept. 4, 2003.) Accordingly, prosecution history estoppel is not applicable here, and the plaintiffs are not barred from arguing for the application of the doctrine of equivalents.

The essential inquiry under the doctrine is, "Does the accused or process contain elements identical or equivalent to each claimed element of the patented invention?" Warner Jenkinson Co., 520 U.S. at 40. This analysis may be determined under the "triple identity" test--which focuses on the "function served by a particular claim element, the way that element serves that function, and the result thus obtained by that element--or it may be evaluated by inquiring whether the allegedly infringing device or process possess only 'insubstantial differences.'" Id. (emphases added). In Warner Jenkinson Co., the Supreme Court observed that the triple identity test is better suited for mechanical devices than for other products or processes. Thus, the more suitable framework here is to inquire whether the defendants' products contain only "insubstantial differences" from the plaintiffs' products. Under either framework, "[t]he

determination of equivalence should be applied as an objective inquiry on an element-by-element basis." Id. "[E]quivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case." Graver Tank & Mfg. Co. v. Linde Air Prods. Co. (Graver II), 339 U.S. 605, 609, 70 S.Ct. 854, 94 L.Ed. 1097 (1950).

"A finding of equivalence is a determination of fact." Graver Tanks & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 65, 609 (1950). "[E]quivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case." Johnson & Johnson Assocs. Inc. v. R.E. Serv. Co. Inc., 285 F.3d 1046, 1053 (Fed.Cir.2002).

The facts before the Supreme Court in Warner Jenkinson Co. are similar to those here. There, the patent at issue covered an ultrafiltration process that operated at a "pH from approximately 6 .0 to 9.0." See Warner Jenkinson Co., 520 U.S. at 22. The alleged infringer used an ultrafiltration process having a pH of 5.0. Id. The Supreme Court held in that case that, as long as prosecution history estoppel did not apply, the doctrine of equivalents could be applied. Based upon this holding and the Supreme Court's view that a jury reasonably could find a pH of 5.0 equivalent to a pH of 6.0-9.0, the court sees no reason why an osmolarity of between 349 and 377 mOsmol/L might not be considered equivalent to an osmolarity of between 385 and 515 mOsmol/L.

Furthermore, although the Supreme Court ruled that intent is irrelevant to the application of the doctrine of equivalents, the plaintiffs have submitted evidence that the defendants developed their solutions by copying the plaintiffs' solutions precisely except that they lowered the osmolarity of the solutions to just under the ranges claimed by the '515 patent. (See Memo of Charles Wall, dated June 2, 1998, Pla. Ex. L; Letter by Robert Veal, dated Aug. 14, 1998, Pla. Ex. G.) This evidence is sufficient to invoke the doctrine of equivalents, which is designed to ensnare exactly "the unscrupulous copyist [who] make[s] unimportant and

insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law." Graver Tanks & Mfg., 339 U.S. at 605. If a jury determined that, as a factual matter, an osmolarity of 349-377 mOsmol/L constitutes an insubstantial difference from an osmolarity of 385-515 mOsmol/L, the jury reasonably could find that the defendants infringed the '515 patent as it read prior to the issuance of the COC.

In response, the defendants have submitted the statements of Charles Wall, who asserts that Buckberg misread the prior art by failing to appreciate that the optimal osmolarity for cardioplegia is significantly below the '515 patent's claimed ranges of 400-500 mOsmol/L. (See Wall Decl. ¶ 9.) Based upon this assertion, Wall claims that the alterations of his solutions are not equivalents but instead constitute substantial improvements on the cardioplegia. (Id.)

This conflicting evidence creates a question of fact to be resolved at trial. Therefore, because prosecution history estoppel cannot apply in this case, the plaintiffs may proceed on their infringement claims based upon the '515 patent as it read prior to the issuance of the COC. Even though the defendants' solutions did not literally infringe the '515 patent prior to the issuance of the COC, the plaintiffs may adduce proof that the osmolarity of the defendants' solutions of between 349 to 377 mOsmol/L is equivalent to the claimed range of between 385 and 515 mOsmol/L. Accordingly, the defendants' motion for summary judgment on the plaintiffs' claims of infringement of the patent as it read prior to the issuance of the COC are due to be, and hereby are, DENIED.[21]

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[21] Because summary judgment as to infringement is denied, it necessarily follows that the plaintiffs' motion for summary judgment as to whether the infringement was willful also is DENIED.

E. Infringement Following the Issuance of the COC

The plaintiffs have moved for summary judgment on their claims of infringement of the '515 patent as amended by the COC. The tests performed by Drs. Holman and Digerness indicate that the defendants' solutions 1, 7, 9, 11, 12, 13, and 14 come within the claimed ranges of the patent as to every element.

Plaintiffs' evidence shows that solutions 1, 7, 9, 11, 13, and 14 had a calcium concentration between 90-199 umol. This is within the '515 patent's claimed range of 50-300 umol, and the defendants have presented no evidence to the contrary. Plaintiffs' evidence shows that solutions 1, 7, 9, 11, 13, and 14 had a glucose concentration of between 639 and 934 mg%. This is within the ' 515 patent's claimed range of 400-1000 mg%, and the defendants have presented no evidence to the contrary. Plaintiffs' evidence shows that solutions 1, 7, 9, 11, 13, and 14 had an amino acid concentration of between 24.2 and 26.5 mmol/L in even proportions of glutamate and aspartate. This is within the '515 patent's claimed range 10-30 mmol/L of aspartate and between 10-30 mmol/L of glutamate, and the defendants have presented no evidence to the contrary. Plaintiffs' evidence shows that solutions 1, 7, 9, 11, 13, and 14 had a pH of between 7.353 and 7.603. This comes within the claimed pH range of 7.5 and 7.7 pH, and the defendants have presented no evidence to the contrary. Plaintiffs' evidence shows that solutions 1, 7, 9, 11, 13, and 14 had an osmolality of between 385 and 398 mOsmol/kg. This is within the '515 patent's claimed range 385 to 515 mOsmol/kg, and the defendants have presented no evidence to the contrary.

Thus, the undisputed evidence shows that the defendants directly infringe the '515 patent as to claims 13 through 17. As to these claims, the defendants' infringement is direct because the defendants manufacture and sell crystalloid cardioplegic solutions which are adapted to be diluted with blood at a 1 to 4 ratio. (See '515 patent claims 13-17; Holman Decl. at ¶ 2.) With respect to claims 1

through 12 and 18, the defendants' infringement is contributory because they sell their cardioplegia products with the intent that the customers will mix them with blood at a 1 to 4 ratio, thereby bringing the solution within the scope of '515 patent's claims.[22]

The undisputed evidence shows, therefore, that the defendants are liable for direct and contributory infringement of the '515 patent as amended by the COC. However, because the court already has ruled that the defendants may present evidence at trial challenging the validity of the COC, the court cannot grant summary judgment on infringement at this time. Instead, the Court will grant summary judgment to the plaintiffs only in part and deny it in part. The plaintiffs' motion for summary judgment is GRANTED IN PART as to the issue of whether the defendants are liable for infringement of the '515 patent as amended by the COC, provided that the COC is valid. The motion is DENIED IN PART insofar as the validity of the COC is a question of fact to be determined at trial.

Similarly, the court will grant in part and deny in part the plaintiffs' motion for summary judgment on their claim that the defendants willfully infringed the '515 patent. The plaintiffs claim that the defendants' infringement of the patent was willful and seek to recover the treble damages authorized by statute for willful infringement. See 35 U.S.C.A. § 284.

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[22] To be contributorily liable for infringement, it must be shown that (1) the defendants sold solutions comprising a material part of the patented invention; (2) the defendants knew the solutions sold were especially made for use in practicing the patented invention; and (3) the solutions sold were not a staple article or commodity of commerce suitable for substantial noninfringing use. *See* 35 U.S.C.A. § 271(c). Here, the memorandum written by Charles Wall, dated June 2, 1998 (Pla.Ex. L), shows that the defendants intended their customers to mix ACS's solutions with blood at a 1 to 4 ratio, which would produce cardioplegic solutions used for the treatment of human hearts within the claimed ranges of the '515 patent.

The undisputed evidence indicates that the defendants directly copied the plaintiffs' patented solutions in developing their products. (Wall Dep. at 29- 30, 48; Memo of Charles Wall, dated June 2, 1998.) This is strong evidence of willful infringement. See Stryker Corp. v. Intermedics Orthopedics, Inc., 96 F.3d 1409, 1414 (Fed.Cir.1996). The only evidence rebutting a finding of willfulness is the opinion letter that the defendants obtained from their counsel, Robert Veal. Ordinarily, an opinion letter from counsel will insulate an infringer from a charge of willful infringement if the opinion of counsel is both favorable and competent. See Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1363 (Fed.Cir.1998).

Here, however, defendants' counsel, Robert Veal, advised the defendants only as to the '515 patent as it read prior to the issuance of the COC.[23] The defendants have submitted no evidence that they obtained a competent opinion from counsel that would insulate them from liability for infringement of the corrected patent. Accordingly, there is no dispute of fact as to the willfulness of the defendants' infringement of the '515 patent following the issuance of the COC. The court therefore will, and hereby does, GRANT IN PART summary judgment as to the willfulness of the defendants' infringement of the '515 patent following the issuance of the COC, provided that at trial the COC is found to be valid. The plaintiffs' motion for summary judgment on

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[23] In his opinion letter, Veal advised the defendants to keep the ranges of the constituent elements of their solutions "significantly out of the specified ranges" of the '515 patent. Veal opined that an osmolarity of 360 mOsmol/L would qualify as significantly outside of the '515 patent's claimed range. The plaintiffs argue that the defendants failed to adhere to Veal's advice because the undisputed evidence here indicates that the defendants' products contained osmolarities of as high as 377 mOsmol/L. Because the court denied summary judgment on the plaintiffs' claims of infringement prior to the issuance of the COC, the court does not need to resolve at this time whether Veal's letter constitutes a defense to willful infringement of the '515 patent prior to the issuance of the COC.

its claim that the defendants' infringement of the patent was willful is in all other respects DENIED.

VI.

Counterclaims

The plaintiffs move for summary judgment on the defendants' counterclaims of (1) false marking under the False Marking Statute, 35 U.S.C. § 292(a) ("Section 292") and (2) false advertising under the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). Each motion is addressed in turn.

A. Facts

In support of the counterclaims of false marking and false advertising, the defendants offer expert reports from Dr. Stanley B. Digerness and Dr. Hal Peterson. These expert reports are discussed at length supra. The defendants rely specifically on the results in each report for the osmolalities of samples of the Buckberg Solution tested. As described above, the Buckberg Solution consists of an amino acid enriched cardioplegic solution having (1) a calcium ion concentration of between 50-300 umol; (2) a concentration of metabolizable substrate between about 400-1000 mg%; and (3) an osmolality of between about 400-500 mOsmol.[24] It is not disputed that the plaintiffs mark all amino enriched cardioplegic solutions as being covered by the '515 patent.

B. False Marking

Count II of the defendants' counterclaim alleges false marking under Section 292. Section 292 is a private attorney general statute that allows recovery of penal damages against anyone who fraudulently misrepresents that a product is subject to a patent. The damages awarded under Section 292 are shared equally with the government. See 35 U.S.C. § 292(b).

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[24] In the *Markman* Order dated May 2, 2002, the court ruled that an osmolality of "between about 400-500 mOsmol" encompasses osmolalities "from 385-515."

The threshold for establishing a successful Section 292 claim is extremely high. Brose v. Sears, Roebuck, & Co., 455 F.2d 763, 768 (5th Cir.1972).[25] Both the language of Section 292 and the binding authority in this Circuit place on the defendants the burden to plead and produce facts demonstrating that the plaintiffs, in marking the solution with the '515 patent, had the specific intent to deceive the public into believing something that the plaintiffs knew to be false. Id. See also Clontech Laboratories, Inc. v. Invitrogen Corp., 406 F.3d 1347, 1355 (Fed.Cir.2005) (intent is a key element under a Section 292 claim); Arcadia Machine & Tool, Inc. v. Sturm, 786 F.2d 1124, 1125 (Fed.Cir.1986) (mismarking must have been done for the purpose of deceiving the public); Mayview Corp. v. Rodstein, 620 F.2d 1347, 1359 (9th Cir.1980) (same). In order to demonstrate an intent to deceive, the defendants must show by a preponderance of the evidence that the plaintiffs "did not have an honest good faith belief in marking its products." Clontech Laboratories, Inc. v. Invitrogen Corp., 406 F.3d 1347, 1355 (Fed.Cir.2005) (citing Brose v. Sears, Roebuck, & Co., 455 F.2d 763, 768- 769 (5th Cir.1972)).

The sole issue for this court to consider in analyzing the counterclaim for false marking is whether or not the defendants have established, through a preponderance of the evidence, that the plaintiffs manifested the intent to deceive when marking the cardioplegic solutions that tested outside the acceptable osmolality range for the '515 patent. Because the court finds that the defendants fail to meet its burden of offering evidence that demonstrates an intent to deceive on the part of the plaintiffs, the Section 292 claim fails.

The Eleventh Circuit has "adopted the formulation that an honest, though mistaken, mismarking of an article would not trigger liability under [Section 292]." Clontech

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[25] The Eleventh Circuit, in *Bonner v. City of Prichard*, 661 F.2d 1206, 1207 (11th Cir.1981) (en banc), adopted as precedent decisions of the former Fifth Circuit rendered prior to October 1, 1981.

Laboratories, Inc. v. Invitrogen Corp., 406 F.3d 1347, 1352 (Fed.Cir.2005) (citing Brose v. Sears, Roebuck and Co., 455 F.2d 763, 768-769 (5th Cir.1972)). Section 292 is not a statute of strict liability for mismarking. Id. "Intent to deceive is a state of mind arising when a party acts with sufficient knowledge that what it is saying is not so and consequently that the recipient of its saying will be misled into thinking that the statement is true." Clontech 406 F.3d 1347 at 1352 (citing Seven Cases v. United States, 239 U.S. 510, 517-517, 36 S.Ct. 190, 60 L.Ed. 411 (1916)).

Intent to deceive is proved when (1) the patent does not cover the marked article; and (2) the differences between the mismarked article and a properly marked article are "so plain that no one in good faith" could think otherwise.[26] Brose v. Sears, Roebuck and Co., 455 F.2d 763, 768 (5th Cir.1972).

> We can assume that if a device claimed to be covered by license of a cited patent is so obviously not revealed by it as the patentese world would view it, the use of such a legend would be mismarking. But where the device is within the specific field covered by the patent and uses materials and methods similar to the technical patent disclosures, the licensee's use in good faith reliance on the license is not to be transmuted into an evil purpose to deceive the public merely on proof and finding that for one or more or all of the reasons skilled patent advocates could think up, the embodiment in question does "not read on" or is not an "infringement" of the cited patent. But this presupposes that the private attorney general has established that the device is not within the patent.

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[26] Claims brought under Section 292 as part of a strategic plan in pending patent litigation are not favored. See *Brose v. Sears, Roebuck and Co.*, 455 F.2d 763, 768 (5th Cir.1972) ("It is at this point that the law-perhaps out of distaste for blood money suits-compels a positive showing. For here not only are objective physical facts involved. Here are questions of motive, purpose and attitudes.").

> Only at that time does the good faith purpose or motive of the marker of a license to a cited patent come into question. Id. at 768-769.

The defendants fail to meet their burden of proof under the first element of the intent test in Brose; therefore the court need not consider the merits of the present case under the second element of the test.

It is undisputed that the plaintiffs mark all their amino enriched cardioplegic solutions with the '515 patent and that the acceptable osmolality range covered under the patent is between 385-515 mOsmol.

The defendants claim that they need not test the plaintiffs' marked solutions to determine that the solutions fall outside the range of the '515 patent because the plaintiffs' own tests demonstrate that fact. See Defendants' Memorandum in Opposition to Plaintiffs' MSJ No. 3 False Marking and False Advertising at 16. The defendants do not challenge that the Buckberg Solution marked by the plaintiffs contains a calcium ion concentration of between 50-300 umol and a concentration of metabolizable substrate between 400-1000 mg% as is required under the patent; rather, the defendants solely posit that certain marked containers of solution fall outside the '515 patent osmolality range of "about 400-500 mOsmol." An examination of the evidence is contrary to the defendants' position. None of the plaintiffs' tests show an osmolality range of the plaintiffs' amino enriched cardioplegic solution outside the patent range of "about 400-500 mOsmol."

The bulk of the defendants' argument and evidence that the plaintiffs' marked solutions fall outside of the '515 patent concern the osmolarity of the plaintiffs' marked solution. As arguments related to the osmolarity of the

plaintiffs' solution have been expressly rejected by this court they will not be considered.[27]

The defendants have not satisfied their burden under the first element of the test in Brose. In addition, the court notes that the defendants' counterclaim fails under the second element of a Brose analysis. The differences between a mismarked solution falling outside of the osmolality range of the '515 patent and a properly marked solution are so negligible that no one in good faith could find that the plain differences between the two solutions reveal an intent to deceive on the part of the plaintiffs. A variation in the osmolality range of a marked solution coupled with the lack of evidence establishing that the plaintiffs' marked solution does not contain a calcium ion concentration of between 50-300 umol or that the marked solution does not contain a concentration of metabolizable substrate between 400-1000 mg% as is required under the patent leads the court to hold that, even if there is a variation in the osmolality range of the marked solution outside of the '515 patent parameters, such a variation does not rise to the level of an intent to deceive under the second element of the test in Brose. Accordingly, the plaintiffs' motion for summary judgment on the defendants' claim of false marking is due to be, and hereby is, GRANTED.

C. False Advertising

Count III of the defendants' counterclaim alleges that the plaintiffs' marking of its amino acid enriched solutions with the '515 patent comprises false advertising actionable under the Lanham Act.

"It is well-settled that no proof of intent or willfulness is required to establish a violation of the Lanham Act ... for false advertising." Vector Products, Inc. v. Hartford Fire Ins. Co., 397 F.3d 1316, 1319 (11th Cir.2005).

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[27] As previously discussed, the court's *Markman* Order dated May 2, 2002, held that claims involving the '515 patent must be analyzed using the term "osmolality" and not "osmolarity."

To succeed on a false advertising claim under the Lanham Act, a defendant must show that: (1) the plaintiff made false or misleading statements about its product in an advertisement; (2) the advertisement actually deceived, or had the tendency to deceive, the targeted audience; (3) the deception is material; (4) the plaintiffs' advertised product traveled in interstate commerce; and (5) the defendant has been or is likely to be injured as a result of the false or misleading advertisements." See Hyman v. Nationwide Mut. Fire Ins. Co., 304 F.3d 1179, 1196 (11th Cir.2002). The failure of the defendants to satisfy their burden with respect to any one of the foregoing elements warrants summary judgment in favor of the plaintiffs. See Laughlin Products, Inc. v. ETS, Inc., 257 F.Supp.2d 863 (N.D.Tex.2002) (the plaintiffs need "only show that [defendants] who bear the burden to prove, have adduced no evidence to support an essential element of the case.").

The defendants have not offered any facts and this court cannot locate any evidence in the record showing that: (1) the plaintiffs marked its amino enriched cardioplegic solutions as being patented; (2) the marking of the plaintiffs' solutions actually deceived or had the tendency to deceive the public; or (3) that any alleged deceptive marking would be material in that the marking somehow influenced customers' purchasing decisions. The parties concede that the marked solutions are sold and transported as a part of interstate commerce. Because the first three elements of the test articulated in Hyman are not satisfied, the court will not provide analysis under the moot fifth element as to whether or not the defendants have suffered an injury as a result of hypothetical false advertising on the part of the plaintiffs.[28]

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[28] The plaintiffs and defendants reference the court to *Zenith Elect. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1348 (Fed.Cir.1999), in order to add an additional element for analysis to the defendants' Lanham Act claim for false advertising that the plaintiffs' alleged marketplace activity in support of the '515 patent "must have been undertaken in bad faith." As neither party cited to Eleventh Circuit or U.S. Supreme Court precedent

Accordingly, the plaintiffs' motion for summary judgment on the defendants' claim of false advertising under the Lanham Act is due to be, and hereby is, GRANTED.

This opinion shall be carried out by a separate Order.

DONE and ORDERED this 13th Day of January, 2006

VIRGINIA EMERSON HOPKINS
United States District Judge

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on this issue and the court, through its own examination, has not located a binding decision relating to the element of "bad faith" discussed in *Zenith*, the court is unwilling to venture beyond the Lanham Act precedent of this Circuit.

# ASSISTANT SECRETARY OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES, DETERMINATION OF PATENT RIGHTS REFERENCE NO. G-237-85, DATED SEPTEMBER 23, 1987

DEPARTMENT OF HE/ TH & HUMAN SERVICES — Public Health Service

Our Ref: G-237-85

Office of the Assistant Secretary for Health
Washington DC 20201

SEP 23 1987

Dr. Gerald D. Buckberg
Department of Surgery
UCLA School of Medicine
The Center for the Health Sciences
Los Angeles, CA 90024-1741

Re: Waiver of Patent Rights in BUCKBERG, "Improved Cardioplegic Solution"

Dear Dr. Buckberg:

Reference is made to the subject invention which was developed by you at the University of California with support from the National Institutes of Health grant number HL-16292. Reference is also made to your petition in which you request that you be permitted to acquire the patent rights to the invention. The University has no objection to your obtaining a waiver of the patent rights from this Department.

In considering the request for a determination under 35 U.S.C. 202(d), as promulgated under 37 C.F.R. 401.9, it is my determination that (1) the invention has been evaluated, and it has been concluded that the Government has insufficient interest in the invention to retain the patent rights; (2) the inventor, Dr. Gerald D. Buckberg, is free to retain and administer the patent rights to the invention in accordance with the requirements of 37 C.F.R. 401.9; and (3) the inventor shall grant to the Government of the United States a nonexclusive, irrevocable, royalty-free license to use the invention for governmental purposes. The form of license to be granted is enclosed.

If the foregoing determination is acceptable to you and the University of California, please indicate your acceptance in the spaces provided below and return the fully executed copy to the Patent Branch, c/o National Institutes of Health, Westwood Building, Room 5A03, Bethesda, MD 20892. Executed copies of the license required by this determination should be submitted to the Patent Branch as soon as possible. This determination will become effective upon receipt of the executed copy.

Sincerely yours,

Robert E. Windom, Ph.D.
Assistant Secretary for Health

Accepted: _____
Dr. Gerald D. Buckberg

Accepted: The University of California
By: _____
Title DIRECTOR
Date: PATENT, TRADEMARK AND COPYRIGHT OFFICE

Encl.

cc: Beatrice Bryan-Dietrick

BEST AVAILABLE COPY

## CONSTITUTIONAL PROVISIONS, STATUTES, AND REGULATIONS

UNITED STATES CONSTITUTION:

ARTICLE III, Section. 2

The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;--to all Cases affecting Ambassadors, other public Ministers and Consuls;--to all Cases of admiralty and maritime Jurisdiction;--to Controversies to which the United States shall be a Party;--to Controversies between two or more States;-- between a State and Citizens of another State;--between Citizens of different States;--between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

TITLE 35 UNITED STATES CODE

§ 100. Definitions

When used in this title unless the context otherwise indicates--

(a) The term "invention" means invention or discovery.

(b) The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

(c) The terms "United States" and "this country" mean the United States of America, its territories and possessions.

(d) The word "patentee" includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.

(e) The term "third-party requester" means a person requesting ex parte reexamination under section 302 or inter partes reexamination under section 311 who is not the patent owner.

§ 200. Policy and objective

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

§ 201. Definitions

As used in this chapter--

(a) The term "Federal agency" means any executive agency as defined in section 105 of title 5, and the military departments as defined by section 102 of title 5.

(b) The term "funding agreement" means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined.

(c) The term "contractor" means any person, small business firm, or nonprofit organization that is a party to a funding agreement.

(d) The term "invention" means any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(e) The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, That in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.

(f) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

(g) The term "made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(h) The term "small business firm" means a small business concern as defined at section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(i) The term "nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c) ) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a) ) or any nonprofit

scientific or educational organization qualified under a State nonprofit organization statute.

§ 202 Disposition of rights.

(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: *Provided, however,* That a funding agreement may provide otherwise (i) when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government, (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter, (iii) when it is determined by a Government authority which is authorized by statute or Executive order to conduct foreign intelligence or counterintelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security of such activities, or (iv) when the funding agreement includes the operation of a Government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above two programs of the Department of Energy. The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter.

(b)

(1) The rights of the Government under subsection (a) shall not be exercised by a Federal agency unless it first determines that at least one of the conditions identified in

clauses (i) through (iii) of subsection (a) exists. Except in the case of subsection (a)(iii), the agency shall file with the Secretary of Commerce, within thirty days after the award of the applicable funding agreement, a copy of such determination. In the case of a determination under subsection (a)(ii), the statement shall include an analysis justifying the determination. In the case of determinations applicable to funding agreements with small business firms, copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy, and recommend corrective actions.

(2) Whenever the Administrator of the Office of Federal Procurement Policy has determined that one or more Federal agencies are utilizing the authority of clause (i) or (ii) of subsection (a) of this section in a manner that is contrary to the policies and objectives of this chapter the Administrator is authorized to issue regulations describing classes of situations in which agencies may not exercise the authorities of those clauses.

(3) At least once every 5 years, the Comptroller General shall transmit a report to the Committees on the Judiciary of the Senate and House of Representatives on the manner in which this chapter is being implemented by the agencies and on such other aspects of Government patent policies and practices with respect to federally funded inventions as the Comptroller General believes appropriate.

(4) If the contractor believes that a determination is contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency, the determination shall be subject to the section 203(b).

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: *Provided*, That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained in the United States, the period for election may be shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory period: And *provided further*, That the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.

(3) That a contractor electing rights in a subject invention agrees to file a patent application prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and shall thereafter file corresponding patent applications in other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or

have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreements relating to weapons development and production.

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: *Provided*, That any such information, as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.

(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

(7) In the case of a nonprofit organization, (A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor); (B) a requirement that the contractor share royalties with

the inventor; (C) except with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research, or education; (D) a requirement that, except where it proves infeasible after a reasonable inquiry, in the licensing of subject inventions shall be given to small business firms; and (E) with respect to a funding agreement for the operation of a Government-owned-contractor-operator facility, requirements (i) that after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year, up to an amount equal to 5 percent of the annual budget of the facility, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility provided that if said balance exceeds 5 percent of the annual budget of the facility, that 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent shall be used for the same purposes as described above in this clause (D); and (ii) that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

(8) The requirements of sections 203 and 204 of this chapter.

(d) If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the

contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

(e) In any case when a Federal employee is a coinventor of any invention made with a nonprofit organization, a small business firm, or a non-Federal inventor, the Federal agency employing such coinventor may, for the purpose of consolidating rights in the invention and if it finds that it would expedite the development of the invention-

(1) license or assign whatever rights it may acquire in the subject invention to the nonprofit organization, small business firm, or non-Federal inventor in accordance with the provisions of this chapter; or

(2) acquire any rights in the subject invention from the nonprofit organization, small business firm, or non-Federal inventor, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction and no other transaction under this chapter is conditioned on such acquisition.

(f)

(1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications required by this paragraph.

(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines that the use of the invention by others is necessary for the practice of a subject invention or for the

use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

§ 203. March-in rights

(a) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such--

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject

invention in the United States is in breach of its agreement obtained pursuant to section 204.

(b) A determination pursuant to this section or section 202(b)(4) shall not be subject to the Contract Disputes Act (41 U.S.C. § 601 et seq.). An administrative appeals procedure shall be established by regulations promulgated in accordance with section 206. Additionally, any contractor, inventor, assignee, or exclusive licensee adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Court of Federal Claims, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand or modify, as appropriate, the determination of the Federal agency. In cases described in paragraphs (1) and (3) of subsection (a), the agency's determination shall be held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence.

§ 204. Preference for United States industry

Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

§ 205. Confidentiality

Federal agencies are authorized to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title, or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed. Furthermore, Federal agencies shall not be required to release copies of any document which is part of an application for patent filed with the United States Patent and Trademark Office or with any foreign patent office.

§ 206. Uniform clauses and regulations

The Secretary of Commerce may issue regulations which may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and shall establish standard funding agreement provisions required under this chapter. The regulations and the standard funding agreement shall be subject to public comment before their issuance.

§ 281. Remedy for Infringement of Patent

A patentee shall have remedy by civil action for infringement of his patent.

TITLE 37 CODE OF FEDERAL REGULATIONS

§ 401.9 Retention of Rights by Contractor Employee Inventor.

Agencies which allow an employee/inventor of the contractor to retain rights to a subject invention made under a funding agreement with a small business firm or nonprofit organization contractor, as authorized by 35 U.S.C. 202(d), will impose upon the inventor at least those conditions that would apply to a small business firm contractor under paragraphs (d)(1) and (3); (f)(4); (h); (i); and (j) of the clause at § 401.14(a).

§ 401.11 Appeals.

(a) As used in this section, the term "standard clause" means the clause at § 401.14 of this part and the clauses previously prescribed by either OMB Circular A-124 or OMB Bulletin 81-22.

(b) The agency official initially authorized to take any of the following actions shall provide the contractor with a written statement of the basis for his or her action at the time the action is taken, including any relevant facts that were relied upon in taking the action.

(1) A refusal to grant an extension under paragraph (c)(4) of the standard clauses.

(2) A request for a conveyance of title under paragraph (d) of the standard clauses.

(3) A refusal to grant a waiver under paragraph (i) of the standard clauses.

(4) A refusal to approve an assignment under paragraph (k)(1) of the standard clauses.

(5) A refusal to grant an extension of the exclusive license period under paragraph (k)(2) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22.

(c) Each agency shall establish and publish procedures under which any of the agency actions listed in paragraph (b) of this section may be appealed to the head of the agency or designee. Review at this level shall consider both the factual and legal basis for the actions and its consistency with the policy and objectives of 35 U.S.C. 200-206.

(d) Appeals procedures established under paragraph (c) of this section shall include administrative due process procedures and standards for fact-finding at least comparable to those set forth in § 401.6 (e) through (g) whenever there is a dispute as to the factual basis for an agency request for a conveyance of title under paragraph (d) of the standard clause, including any dispute as to whether or not an invention is a subject invention.

(e) To the extent that any of the actions described in paragraph (b) of this section are subject to appeal under the Contract Dispute Act, the procedures under the Act will satisfy the requirements of paragraphs (c) and (d) of this section.

§ 401.14 Standard patent rights clauses.

(a) The following is the standard patent rights clause to be used as specified in § 401.3(a).

Patent Rights (Small Business Firms and Nonprofit Organizations)

(a) Definitions

(1) "Invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(2) "Subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(3) "Practical Application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

(4) "Made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) "Small Business Firm" means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small

Business Administration. For the purpose of this clause, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

(6) "Nonprofit Organization" means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (25 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(b) Allocation of Principal Rights

The Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the Contractor retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(c) Invention disclosure, Election of Title and Filing of Patent Application by Contractor.

(1) The contractor will disclose each subject invention to the Federal Agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been

submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the Contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor.

(2) The Contractor will elect in writing whether or not to retain title to any such invention by notifying the Federal agency within two years of disclosure to the Federal agency. However, in any case where publication, on sale or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The contractor will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The contractor will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the agency, be granted.

(d) Conditions When the Government May Obtain Title

The contractor will convey to the Federal agency, upon written request, title to any subject invention--

(1) If the contractor fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the agency may only

request title within 60 days after learning of the failure of the contractor to disclose or elect within the specified times.

(2) In those countries in which the contractor fails to file patent applications within the times specified in (c) above; provided, however, that if the contractor has filed a patent application in a country after the times specified in (c) above, but prior to its receipt of the written request of the Federal agency, the contractor shall continue to retain title in that country.

(3) In any country in which the contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(e) Minimum Rights to Contractor and Protection of the Contractor Right to File

(1) The contractor will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the contractor fails to disclose the invention within the times specified in (c), above. The contractor's license extends to its domestic subsidiary and affiliates, if any, within the corporate structure of which the contractor is a party and includes the right to grant sublicenses of the same scope to the extent the contractor was legally obligated to do so at the time the contract was awarded. The license is transferable only with the approval of the Federal agency except when transferred to the sucessor of that party of the contractor's business to which the invention pertains.

(2) The contractor's domestic license may be revoked or modified by the funding Federal agency to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions at 37 CFR Part 404 and agency licensing regulations (if any). This license will not be revoked in that field of use or the geographical areas in which the contractor has achieved

practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the funding Federal agency to the extent the contractor, its licensees, or the domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the funding Federal agency will furnish the contractor a written notice of its intention to revoke or modify the license, and the contractor will be allowed thirty days (or such other time as may be authorized by the funding Federal agency for good cause shown by the contractor) after the notice to show cause why the license should not be revoked or modified. The contractor has the right to appeal, in accordance with applicable regulations in 37 CFR Part 404 and agency regulations (if any) concerning the licensing of Government-owned inventions, any decision concerning the revocation or modification of the license.

(f) Contractor Action to Protect the Government's Interest

(1) The contractor agrees to execute or to have executed and promptly deliver to the Federal agency all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the contractor elects to retain title, and (ii) convey title to the Federal agency when requested under paragraph (d) above and to enable the government to obtain patent protection throughout the world in that subject invention.

(2) The contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the contractor each subject invention made under contract in order that the contractor can comply with the disclosure provisions of

paragraph (c), above, and to execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by (c)(1), above. The contractor shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The contractor will notify the Federal agency of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of the response period required by the relevant patent office.

(4) The contractor agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention."

(g) Subcontracts

(1) The contractor will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental or research work to be performed by a small business firm or domestic nonprofit organization. The subcontractor will retain all rights provided for the contractor in this clause, and the contractor will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(2) The contractor will include in all other subcontracts, regardless of tier, for experimental developmental or research work the patent rights clause required by (cite section of agency implementing regulations or FAR).

(3) In the case of subcontracts, at any tier, when the prime award with the Federal agency was a contract (but not a grant or cooperative agreement), the agency, subcontractor, and the contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Federal agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (j) of this clause.

(h) Reporting on Utilization of Subject Inventions

The Contractor agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commerical sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify. The contractor also agrees to provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (j) of this clause. As required by 35 U.S.C. 202(c)(5), the agency agrees it will not disclose such information to persons outside the government without permission of the contractor.

(i) Preference for United States Industry

Notwithstanding any other provision of this clause, the contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency upon a showing by the contractor or

its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commerically feasible.

(j) March-in Rights

The contractor agrees that with respect to any subject invention in which it has acquired title, the Federal agency has the right in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such a request the Federal agency has the right to grant such a license itself if the Federal agency determines that:

(1) Such action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee or licensees; or

(4) Such action is necessary because the agreement required by paragraph (i) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(k) Special Provisions for contracts with Nonprofit organizations

If the contractor is a nonprofit organization, it agrees that:

(1) Rights to a subject invention in the United States may not be assigned without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions, provided that such assignee will be subject to the same provisions as the contractor;

(2) The contractor will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) The balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidential to the administration of subject inventions, will be utilized for the support of scientific research or education; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject invention that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the contractor determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the contractor agrees that the Secretary may review the contractor's licensing program and decisions regarding small business applicants, and the contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary

when the Secretary's review discloses that the contractor could take reasonable steps to implement more effectively the requirements of this paragraph (k)(4).